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LEGAL/REGULATORY PLANNING & ASSESSMENT TOOL

A Healthcare Guide for Pandemic Flu Planning



PLANNING TODAY FOR A PANDEMIC TOMORROW



Supported by a grant from



LEGAL AND REGULATORY
PLANNING & ASSESSMENT TOOL:
A HEALTHCARE GUIDE FOR PANDEMIC FLU PLANNING

PLANNING TODAY FOR A PANDEMIC TOMORROW
PUBLICATION SERIES

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NJHA's *Planning Today for a Pandemic Tomorrow Legal/Regulatory module* is supported by a grant from the New Jersey Department of Health and Senior Services. The module is intended to serve as a planning tool and is not intended to constitute a standard of care. As such, a hospital's pandemic preparedness plan should be tailored to meet its specific needs.

Pandemic Flu Planning Committee

Pamela Berman

Employment Consultant
Cooper Health Systems

John Brede

Director, Materials Management
Southern Ocean County Hospital
President, New Jersey Chapter of Materials Management Society

Patricia Daley

Executive Director
ONE of NJ

George DiFerdinando, MD

Adjunct Professor, Epidemiology
The New Jersey Center for Public Health Preparedness
UMDNJ School of Public Health

Sonny Fitzpatrick

Sales Director
Owens & Minor Distribution, Inc.

Robert Foran

Assistant Vice President, Clinical Support Service
Southern Ocean County Hospital

Joseph Goss, BS, RRT

President
New Jersey Society for Respiratory Care

John Hailperin

Director, Managed Care
Raritan Bay Medical Center

Emro Krasovec

Vice President, Human Resources
Bayshore Community Hospital

Kevin McDonnell

Vice President, Operations
MMS/Caligor

Barbara Montana, MD

Medical Director, Health Emergency Preparedness and Response
New Jersey Department of Health & Senior Services

Amelia Muccio

Director of Disaster Planning
New Jersey Primary Care Association

Jennifer Prazak

Director of Market Management
VHA East Coast L.L.C.

James Pruden, MD

Chairman, Department of Emergency Medicine
St. Joseph Regional Medical Center

Vince Robbins

President and CEO
MONOC

Kathy Roye-Horn, RN, CSC

Director of Infection Control, Nurse Epidemiologist
Hunterdon Medical Center

Lou Sasso

E.M.S. Director
Robert Wood Johnson University Hospital

Jackie Sutton

Director of Pharmacy
Cooper Health System

Valerie Tantum

Special Projects
St. Barnabas Medical Center

Nancy Wilson

Director of Clinical Services/Infection Control
Carrier Clinic

Phyllis Worrell, MICP

Emergency Management Coordinator
Virtua Health

National Reviewers

Christine Grant, JD, MBA

CEO

Infectedetect

Former Commissioner New Jersey
Department of Health and Senior
Services

Dan Hanfling, MD

*Director of Emergency Management
and Disaster Medicine*

Inova Fairfax Hospital

Eric Toner, PhD

Senior Associate

University of Pittsburgh Medical
Center
Center for Biosecurity

James Blumenstock

Chief Program Officer

Association of State and Territorial
Health Officials

James Stevenson,

Pharm. D, FASHP

Pharmacy Director

University of Michigan Health
Systems

Jonathan Links, PhD

Professor

John Hopkins University and Health
System

Additional Reviewers

Alice Guttler, Esq.

*Senior Vice President/Corporate
Counsel*

CentraState Healthcare System

New Jersey Hospital Association Staff

Project Leaders

Valerie Sellers

*Senior Vice President, Health
Planning and Research*

Colleen Picklo

*Operations Manager,
Pandemic Influenza Project
Manager*

NJHA Staff Consultants

Fredrick J. Jacobs, Esq.

General Counsel

Project Consultants

**Steven D. Gravely, J.D.,
M.H.A.**

Partner and Health Care

Practice Group Leader

Troutman & Saunders, LLC

Erin S. Whaley, J.D., M.A.

Associate

Troutman & Saunders, LLC

**Patricia Elliott, J.D.,
M.P.H.**

Office Counsel

Troutman & Saunders, LLC

**Katherine Tanner Smith,
J.D., R.N.**

Associate

Troutman & Saunders, LLC

Stacey Wacknov

Medical Editor

INTRODUCTION

Through the use of a detailed assessment and planning tool, hospitals can review existing policies and procedures, identify gaps, adopt new policies and procedures and generate a pandemic influenza plan that will facilitate a more effective response during a crisis. This tool will assist hospitals in developing and adopting new policies that will be required to protect employees, patients and the hospital itself. The planning and assessment tool identifies critical elements within each module related to hospital operations during an emergency situation. In addition, the tool provides a variety of sample policies and procedures that facilities may elect to use in their planning process.

Critical areas to address when planning for a pandemic include:

| | |
|-----------------|-------------------------------------|
| Clinical Care | Leadership |
| Communication | Legal/Regulatory |
| Ethics | Operations |
| Finance | Psycho-Social |
| Human Resources | Supplies/Logistics/Support Services |

How to Use This Module

Hospitals should form multi-disciplinary work teams to develop policies and procedures relating to each of the critical areas identified above. Diverse perspectives will help ensure that all issues or concerns that may be raised during a pandemic can be brought to the table while in the planning process.

The modules are to be used as a guide to facilitate discussion and to ensure that key points related to a topic such as human resources are identified and addressed in the planning process. Sample policies and/or procedures are provided; these policies and procedures are by no means all inclusive, and hospitals should not interpret the sample policies as what *must* be adopted. Sample policies are provided to assist a hospital in developing a policy that is consistent with the culture and values of the organization. Hospitals are not required to adopt any of the sample policies and procedures; they are intended simply to serve as a resource and guide in the planning process. *They are not reflective of a standard of care.*

Upon completion of the 10 modules reflected in *Planning Today for a Pandemic Tomorrow*, a "cross-walk" will be developed. This cross-walk will provide guidance for other module areas that should be referenced when developing policies and procedures. For example, when examining a Human Resources policy, the Legal and Regulatory module may need to be reviewed.

And finally, the information reflected in the planning and assessment tool modules is intended to be used as a fluid and flexible resource in dealing with the problems associated with a pandemic influenza outbreak. It is based on existing information, therefore hospitals should routinely review their plan to ensure new information is incorporated into policies and procedures as necessary.

LEGAL MODULE

Traditionally, when health care facilities engage in preparedness activities, they focus on operational preparedness; however, because the complex legal and regulatory framework in which health care facilities and providers operate will not “disappear” during a pandemic, it is also critical to focus on the requirements of these laws and regulations. Indeed, recent experiences with SARS and Hurricanes Katrina and Rita demonstrate that, while some laws and regulations are likely to be suspended or waived during a large scale disaster, the majority of legal and regulatory requirements are expected to remain in full force and effect. In addition, during a pandemic, health care facilities will have to comply with a host of additional state and federal laws and regulations. Therefore, “legal preparedness” is an essential component of an organization’s overall pandemic preparedness activities.

Legal preparedness begins with risk mitigation. It is now widely accepted that health care facilities have a duty to prepare for disasters, including influenza pandemic. The failure to develop implementable plans, based on realistic assumptions, is likely to be a breach of this duty and expose health care facilities to liability. A key component of an implementable plan is compliance with all applicable laws and regulations. In addition to the myriad of laws with which they are already familiar, health care facilities must also understand the requirements and contours of the Public Readiness and Emergency Preparedness (PREP) Act; the Pandemic and All Hazards Act; the Federal Volunteer Protection Act; state emergency services laws; emergency health powers acts; quarantine and isolation laws; and Good Samaritan laws. This legal module has been designed to help readers understand not only which laws should be examined, but also the complexities and issues that these laws present for planning efforts.

In the sections that follow, a series of numbered planning tasks are broken down by type of legal issue and operational preparedness activity. The planning tasks walk the reader through the analysis of the relevant law and methods for complying with the law. The planning tasks are discretionary and are representative of the legal issues that should be considered by health care facilities.

These legal issues and operational preparedness activities include:

A. EMERGENCY HEALTH POWERS ACT

- ✓ Initial Planning
- ✓ Commandeering and Closure
- ✓ Healthcare Workers Issues
- ✓ Quarantine and Isolation

B. EMERGENCY SERVICES LAW

- ✓ Initial Planning
- ✓ Control, Use and Closure
- ✓

C. HEALTH CARE FACILITY LICENSURE AND REGULATORY ISSUES

- ✓ Initial Planning
- ✓ Complimentary Services Provided by Health Care Facilities
- ✓ Surge Considerations
- ✓ Medicare Conditions of Participation
- ✓ Treatment and Disposition of the Dead
- ✓ Medication Use
- ✓ Pandemic Influenza Spending Guidelines and Compliance
- ✓ Zoning and Land Use Issues

D. HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)

- ✓ Initial Planning
- ✓ Specific Exceptions and Applications

E. EMERGENCY MEDICAL TREATMENT AND ACTIVE LABOR ACT (EMTALA)

- ✓ Initial Planning
- ✓ Specific Exceptions and Applications

F. STAFFING ISSUES

- ✓ Initial Planning
- ✓ Health Care Provider Licensing Statutes and Regulations – Maximizing Delegable Duties
- ✓ Medical Staff Considerations
- ✓ Provision of Scarce Countermeasures to Health Care Facility Personnel
- ✓ Employee Screening By Health Care Facilities
- ✓ Legal Considerations Related To Contractors
- ✓ Employee Assistance Programs (EAPs)
- ✓ Infrastructure for Decision Making During Disasters

G. ALTERED STANDARDS OF CARE

- ✓ Initial Planning
- ✓ Liability
- ✓ Withdrawal of Care

H. CONTRACT ISSUES

- ✓ Initial Planning
- ✓ Supply Vendors
- ✓ Utilities
- ✓ Third Party Reimbursement
- ✓ Bond and Debt Contracts

I. ALTERNATE CARE SITES

- ✓ Initial Planning
- ✓ Contract Issues Related to Management and Oversight
- ✓ Liability Issues
- ✓
- ✓ Reimbursement

J. VOLUNTEERS

- ✓ Initial Planning
- ✓ Good Samaritan and Other Volunteer Protections
- ✓ EMAC or Other Mutual Aid Agreements

Where applicable, a section titled “New Jersey Examples” immediately follows the planning task section. The numbered examples give a brief description of New Jersey law related to the planning task of the same number. These examples are intended to serve as a helpful resource for counsel to review when advising a health care facility in New Jersey on its legal preparedness. Counsel for health care facilities outside of New Jersey should substitute their own analysis of the applicable state’s statutes and regulations when advising their clients.

This module is not offered as legal advice, and should not be viewed as a substitute for a facility consulting with legal counsel experienced in emergency and disaster law since each health care facility’s situation is unique.

A. EMERGENCY HEALTH POWERS ACT – INITIAL PLANNING

Most states have a set of statutes that govern preparedness, response and recovery for public health emergencies. In many of these statutes, the governor or state health officer (SHO) will be granted authority to declare a public health emergency and will be vested with certain powers as a result of the declaration. These statutes may also contain provisions related to the quarantine and isolation of contagious individuals. In some states, these statutes are collectively referred to as the Emergency Health Powers Act. In other states, these statutes do not have a specific title.

In your plan, consider the following:

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|------------------------------|--|-----------|-------------|-------------|----------------------|-------------------|
| Emergency Declaration | | | | | | |
| 1 | Review the state's Emergency Health Powers Act. | | | | | |
| 2 | Identify if a pandemic can be declared a "public health emergency" under the Emergency Health Powers Act. | | | | | |
| 3 | Identify who, under state law, has the authority to declare a public health emergency. <ul style="list-style-type: none"> • Governor • State health officer • Other | | | | | |

A. EMERGENCY HEALTH POWERS ACT – INITIAL PLANNING CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|------------------------------------|---|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 4 | Identify how a public health emergency is declared and whether legislative ratification is necessary. | | | | | |
| 5 | Identify what, if any, limitations are imposed on this authority (e.g., duration, geographic boundaries). | | | | | |
| 6 | Determine how the health care facility will know that a declaration has been issued. | | | | | |
| 7 | Determine how the health care facility will obtain a copy of the declaration once it is issued. | | | | | |
| EMERGENCY POWERS AND RIGHTS | | | | | | |
| 8 | Identify all provisions of the Emergency Health Powers Act that may impact the health care facility. | | | | | |
| 9 | Identify the scope of the SHO's preparedness power under the Emergency Health Powers Act. | | | | | |

A. EMERGENCY HEALTH POWERS ACT – INITIAL PLANNING CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|--|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 10 | Identify how these powers might impact a health care facility. Consider possible commandeering of the health care facility, seizure of medicines or medical supplies, etc. | | | | | |
| 11 | Ensure familiarity with the scope of all additional rights and powers granted to the governor, SHO, or other governmental officials that are associated with the declaration of a public health emergency. | | | | | |
| 12 | Ensure an understanding of the health care facility's appeal rights to challenge specific governmental actions or orders granted under a public health emergency. | | | | | |
| SUSPENSION OF LAWS AND REGULATIONS | | | | | | |
| 13 | Identify if the Emergency Health Powers Act gives the SHO the authority to suspend state laws or regulations. | | | | | |

A. EMERGENCY HEALTH POWERS ACT – INITIAL PLANNING CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|----|---|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 14 | Identify what state laws or regulations the health care facility would have difficulty complying with during a pandemic, and whether they can be suspended, waived or otherwise modified. (See all other sections of the Legal module.) | | | | | |
| 15 | Develop procedures to enable the health care facility to immediately and appropriately respond to a request from the SHO or governor to identify laws or regulations hindering the health care facility's response efforts in case the government wishes to suspend them. | | | | | |
| 16 | Determine if other persons or agencies within the state government are granted additional rights and powers as a result of the declaration of a public health emergency. | | | | | |
| 17 | Identify how the rights and powers granted others could impact the health care facility. | | | | | |

A. EMERGENCY HEALTH POWERS ACT – INITIAL PLANNING CONTINUED

| INTERACTION WITH OTHER LAWS | | | | | | |
|-----------------------------|---|--|--|--|--|--|
| 18 | Identify how the Emergency Health Powers Act will interact with the Emergency Services Act, if applicable. | | | | | |
| 19 | Identify how quarantine and isolation laws interact with the Emergency Health Powers Act, if applicable. See Emergency Health Powers Act, Section Quarantine and Isolation. | | | | | |

EMERGENCY HEALTH POWERS ACT – INITIAL PLANNING

NEW JERSEY EXAMPLES

Emergency Declarations

1. The New Jersey Emergency Health Powers Act is located at N.J.S.A. § 26:13-1 et seq. (2008).

See also the *New Jersey Influenza Pandemic Plan* (June 2008), which summarizes the state's legal authorities during a pandemic in Section II. "Authorities" and Section IV. "Planning Assumptions," addressing in part how those powers will be used (available at: http://www.state.nj.us/health/flu/panflu_plan.shtml).

2. In New Jersey, a "public health emergency" is, among other things, caused by the appearance of a novel biological agent and poses a high probability of a large number of deaths, illness or injuries in the affected population (N.J.S.A. § 26:13-2 (2008)). A "biological agent" includes a virus that is naturally occurring. A pandemic caused by the influenza virus can be a public health emergency under New Jersey's Emergency Health Powers Act.

Various provisions of the New Jersey Emergency Health Powers Act switch between use of the term "declared public health emergency" and "state of public health emergency." It is unclear whether this distinction has any significance, but health care facilities should consider seeking clarification from the Department of Health and Senior Services or the attorney general's office.

3. Pursuant to New Jersey's Emergency Health Powers Act, the governor, in consultation with the commissioner of Health and Senior Services and the director of the State Office of Emergency Management, may declare a public health emergency. The governor must issue an order that specifies the nature of the public health emergency; the geographic area subject to the declaration; the conditions that have brought about the public health emergency; and the expected duration of the state of public health emergency (see N.J.S.A. § 26:13-3 (2008)).

Emergency Powers and Rights

9. Under the New Jersey Emergency Health Powers Act, if the governor declares an emergency in accordance with the Civilian Defense Act and Disaster Control Act (N.J.S.A. § App.A:9-33 et seq. (2008)), the governor is then authorized to exercise the powers granted to the commissioner pursuant to the Emergency Health Powers Act. To the extent that an influenza pandemic is both a declared public health emergency and a declared emergency under N.J.S.A. § App.A:9-33 (2008), it is unclear exactly who will be exercising the powers granted in the Emergency Health Powers Act – the governor or the commissioner.

For the remainder of the discussion, we will use the term “commissioner” when discussing the New Jersey Emergency Health Powers Act, but understand that this may either be the commissioner or the governor.

10. N.J.S.A. § 26:13-6(c) (2008) gives the commissioner the ability to “identify all or part of a hospital or other location as an emergency health care center.” Health care facilities should consider discussions with the Department of Health and Senior Services about where it foresees establishing emergency health care centers and how these centers will be managed, operated and staffed.

11. N.J.S.A. § 26:13-21 (2008) describes the commissioner’s preparedness powers and use of Local Information Network and Communications System (LINCS) agencies. Health care facilities should understand how their planning efforts interact with, and are impacted by, LINCS agencies.

LINCS agencies will, at the direction of the commissioner, serve as planning and coordinating agencies for all municipalities and local health agencies within a county or city, as applicable (N.J.S.A. § 26:13-21 (2008)).

The secretary of agriculture will have the authority to investigate pandemic influenza to the extent that it involves animals under the jurisdiction of the Department of Agriculture (N.J.S.A. § 26:13-3(d) (2008)).

Suspension of Laws and Regulations

13. The New Jersey Emergency Health Powers Act does not give the commissioner the explicit authority to suspend state laws or regulations, but it does direct him/her to “confer with the Commissioner of Banking and Insurance to request that the Department of Banking and Insurance waive regulations requiring compliance by a health care provider or health care facility with a managed care plan’s administrative protocols, including but not limited to, prior authorization and pre-certification” (N.J.S.A. § 26:13-9(b)(5) (2008)). As a result, during a public health emergency, it will be important for health care facilities to not only monitor the orders issued by the commissioner of NJDHSS, but also the orders issued by the commissioner of Banking and Insurance. Counsel should be familiar with the commissioner of Banking and Insurance’s ability to suspend such regulations and the process for such actions.

In New Jersey, the commissioner of Banking and Insurance may have the ability to waive certain administrative regulations related to managed care plans (N.J.S.A. § 26:13-9(b)(5) (2008)). To the extent that such waiver would help the health care facility's financial continuity of operations plan, the extent and mechanism of the waiver should be understood.

Interaction With Other Laws

18. The commissioner's response to a public health emergency is done in coordination with the State Office of Emergency Management and in accordance with the State Emergency Operations Plan (N.J.S.A. § 26:13-3 (2008)). This means that not only do health care facilities have to be familiar with the Emergency Health Powers Act; they should also be familiar with the State Emergency Operations Plan.

A. EMERGENCY HEALTH POWERS ACT – **COMMANDEERING AND CLOSURE**

The State Emergency Health Powers Act may authorize the government to commandeer or close health care facilities, as well as confiscate medicines, supplies and equipment. Health care facilities should carefully understand the processes for how such decisions will be made; how to appeal such orders; procedures for re-opening the facility; and how to seek appropriate compensation for governmental use or taking of property. Health care facilities must also develop strategies, such as securing business interruption insurance to mitigate the effects of a closure or confiscation.

In your plan, consider the following:

| ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|------------------------------|--|-------------|-------------|----------------------|-------------------|
| CLOSURE OF FACILITIES | | | | | |
| 1 | Identify who is permitted to close a health care facility under the Emergency Health Powers Act: <ul style="list-style-type: none"> • Governor • State health officer • Local health officer • Other | | | | |
| 2 | Identify if there is a process to appeal closure under the Act and, if so, what is the process for appeal. | | | | |
| 3 | Identify if an appeal will allow for a stay in the order to close. | | | | |

A. EMERGENCY HEALTH POWERS ACT – COMMANDEERING AND CLOSURE CONTINUED

| ASSIGNMENT | | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|------------------------------|--|-----------|-------------|-------------|----------------------|-------------------|
| CONTROL OF FACILITIES | | | | | | |
| 4 | Identify who is permitted to take control of a health care facility under the Emergency Health Powers Act: <ul style="list-style-type: none"> • Governor • State health officer • Local health officer • Other | | | | | |
| 5 | Identify if there is a process to appeal a governmental decision to assume control of a health care facility under the Act. If so, identify the process for appeal. | | | | | |
| 6 | Identify if an appeal will allow for a stay in the governmental order assuming control of a health care facility. | | | | | |
| 7 | Clarify who is responsible for continued operation post-seizure — the health care facility's current management or the government. | | | | | |

A. EMERGENCY HEALTH POWERS ACT – COMMANDEERING AND CLOSURE CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|--|---|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 8 | Clarify that, upon governmental seizure of the health care facility, the organization has no further liability for acts that occur during the period of seizure. | | | | | |
| CONFISCATE SUPPLIES, EQUIPMENT OR MEDICINES | | | | | | |
| 9 | Identify who is permitted to confiscate a health care facility's supplies, equipment or medication under the Emergency Health Powers Act: <ul style="list-style-type: none"> • Governor • State health officer • Local health officer • Other | | | | | |
| 10 | Identify if there is a process to appeal a governmental order to confiscate a health care facility's supplies, equipment or medication under the Act. If so, identify the process for appeal. | | | | | |
| 11 | Identify if an appeal will allow for a stay in the governmental order to confiscate a health care facility's supplies, equipment or medication. | | | | | |

A. EMERGENCY HEALTH POWERS ACT – COMMANDEERING AND CLOSURE CONTINUED

| ASSIGNMENT | | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|------------------------------------|---|-----------|-------------|-------------|----------------------|-------------------|
| CONTROL OF PERSONS | | | | | | |
| 12 | Identify if the SHO has the authority to require licensed medical professionals to report for work | | | | | |
| MITIGATION AND COMPENSATION | | | | | | |
| 13 | Determine if there is any mechanism for compensation if the state closes or commandeers a health care facility. | | | | | |
| 14 | Determine if the health care facility has business interruption insurance. See Contract Issues, Third Party Reimbursement, of this Legal module. | | | | | |
| 15 | Determine the process for regaining control or re-opening the health care facility after a pandemic. | | | | | |
| 16 | If the SHO has the ability to commandeer the health care facilities and/or its supplies, or can require people to report to work, identify the compensation that is available to the health care facility and/or employees. | | | | | |

EMERGENCY HEALTH POWERS ACT – COMMANDEERING AND CLOSURE

NEW JERSEY EXAMPLES

The *New Jersey Influenza Pandemic Plan* (June 2008), Section VII.C. “Health Care Planning” includes information about the state’s plans for addressing obstacles to health care planning, including command and control of health care resources and the waiver of state regulations (available at: http://www.state.nj.us/health/flu/panflu_plan.shtml).

Closure of Facilities

1. N.J.S.A. § 26:13-8 (2008) gives the commissioner the ability to close, direct and compel the evacuation of, or to cause to be decontaminated, any facility for “which there is reasonable cause to believe that it may endanger the public health.” Within 24 hours of closure of the health care facility, the commissioner must provide the health care facility with a written order specifying the details of the closure.
2. The health care facility subject to a closure order may request a hearing in the Superior Court to contest the order. The Superior Court must hold the hearing within 72 hours of the request, excluding Saturdays, Sundays and legal holidays.
3. It is unclear whether filing to contest the order stays the order. This is a point that should be clarified and understood by all health care facilities.

The health care facility should consider implementing processes and procedures for appealing orders to close the health care facility.

Control of Facilities

4. N.J.S.A. § 26:13-9 (2008) gives the commissioner the ability to take control of a New Jersey health care facility. The commissioner may require a health care facility to provide services or to use its facilities to respond to the public health emergency, “as a condition of licensure, authorization or the ability to continue doing business in the state as a health care facility.”
5. The health care facility subject to an order to transfer management and supervision may request a hearing in the Superior Court to contest the order. The Superior Court must hold the hearing within 72 hours of the request, excluding Saturdays, Sundays and legal holidays.
7. The commissioner, after consultation with the management of the health care facility, may also transfer the management and supervision of the health care facility to the commissioner. In the event of such transfer, the commissioner must use the existing management of the health care facility.

Confiscate Supplies, Equipment or Medicines

9. N.J.S.A. § 26:13-11 (2008) gives the commissioner the power to purchase, obtain, store, distribute, or “take for priority redistribution” any vaccines, antibiotics, or other pharmaceutical agents or medical supplies “as may be reasonable and necessary to respond to the public health emergency.” Moreover, even if the commissioner does not take possession of the supplies, the commissioner has the ability to issue and enforce orders to ration and allocate supplies to respond to a shortage or threatened shortage of the supply. In making these rationing decisions, the commissioner may give “preference to health care providers; disaster response personnel; mortuary staff; and such other persons as the commissioner deems appropriate in order to respond to the public health emergency.”

10. Note this statute does not contain an appeal mechanism so it is unclear whether a health care facility can appeal the commissioner’s decision to confiscate and re-allocate its supplies or pharmaceutical agents. These provisions should be carefully considered when the health care facility is deciding whether to stockpile antivirals or other supplies in anticipation of a pandemic.

Control of Persons

12. N.J.S.A. § 26:13-18 addresses the emergency powers of the commissioner over health care personnel.

Mitigation and Compensation

16. Importantly, if the commissioner invokes these powers, the health care facility will be entitled to the payment of reasonable costs from the State Public Health Emergency Claim Reimbursement Board in accordance with N.J.S.A. § 26:13-24, 25 (2008). The specifics of how “reasonable costs” are calculated are not clear.

A. EMERGENCY HEALTH POWERS ACT – HEALTH CARE WORKER ISSUES

Health care workers are a critical resource during public health emergencies. The State Emergency Health Powers Act gives government the right to require that health care workers in the state assist in the response to a public health emergency. Health care workers compelled to assist are given liability protections in return for their activities planning for and responding to a public health emergency. Health care volunteers are another critical resource available to states to help meet surging demands for medical services during an emergency. Health care facilities should familiarize themselves with the rights and duties of workers during a declared public health emergency. See also Staffing and Volunteers, Sections F and H of the Legal module.

In your plan, consider the following:

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|-------------------------------|---|-----------|-------------|-------------|----------------------|-------------------|
| DUTY TO REPORT TO WORK | | | | | | |
| 1 | Identify if the Emergency Health Powers Act gives the SHO the authority to require licensed medical professionals to report to work. | | | | | |
| 2 | Identify if the Emergency Health Powers Act authorizes license revocations, fines or detention for health care providers who disobey public health officials' orders to work during a pandemic. | | | | | |
| 3 | Evaluate the impact of any collective bargaining agreements on the SHO's authority to require licensed medical professionals to report to work. See HR module. | | | | | |

A. EMERGENCY HEALTH POWERS ACT – HEALTH CARE WORKER ISSUES CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|--|-----------|-------------|-------------|----------------------|-------------------|
| PROVIDING CARE IN A HEALTH CARE FACILITY SETTING | | | | | | |
| 4 | Determine if the Emergency Health Powers Act provides any liability protection or immunity for persons providing care in a health care facility setting during a pandemic. | | | | | |
| 5 | Identify the parameters and limitations of any protections offered under the Emergency Health Powers Act to persons providing care in a health care facility setting. | | | | | |
| 6 | Identify if protections offered under the Emergency Health Powers Act to persons providing care is limited to volunteers or also covers persons who are paid for their services. | | | | | |
| 7 | Identify if the protections offered are limited to those persons licensed to deliver the type of care they are providing during an emergency. | | | | | |

A. EMERGENCY HEALTH POWERS ACT – HEALTH CARE WORKER ISSUES CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|--------------------------|--|-----------|-------------|-------------|----------------------|-------------------|
| USE OF VOLUNTEERS | | | | | | |
| 8 | Identify if the State's Emergency Health Powers Act provides for registration of volunteers. | | | | | |
| 9 | Determine if volunteer workers will be available to health care facilities, or whether they will be used solely by the state in its pandemic response. | | | | | |
| 10 | Develop policies and procedures for incorporating health care volunteers into the health care facility's emergency response plan. See HR module. | | | | | |
| 11 | Prepare for spontaneous unsolicited volunteers to self-deploy to the health care facility; have a mechanism to redirect them to the local or state incident manager. | | | | | |

EMERGENCY HEALTH POWERS ACT - HEALTH CARE WORKER ISSUES

NEW JERSEY EXAMPLES

Duty to Report to Work

1. N.J.S.A. § 26:13-18 (2008) gives the commissioner the ability to “require in-state health care providers to assist in the performance of vaccination, treatment, examination or testing of any individual” during a public health emergency. Pursuant to the same statute, an in-state provider who is required by the commissioner to assist in the response to the public health emergency will not be liable for any civil damages arising out of the care provided in good faith.

The scope of the commissioner’s authority under this provision is unclear. For example, it is uncertain if the commissioner has the power to require a licensed health care provider to report to work at a private health care facility. Individual health care providers and health care facilities should seek to clarify the scope of this power.

2. The New Jersey Emergency Health Powers Act does not appear to impose sanctions on those providers who refuse to work during a public health emergency.

Providing Care in a Health Care Facility Setting

4. N.J.S.A. § 26:13-6(g) (2008) contains immunity from civil damages for volunteer emergency health care workers; public health workers; and support service personnel registered as a volunteer under this section and providing medical care or treatment related to the public health emergency.

N.J.S.A. § 26:13-9(b)(4) (2008) provides immunity for a health care facility that is used or managed by the commissioner during the public health emergency. Note this immunity only applies to civil damages arising from the commissioner’s acts or omissions in providing medical care or treatment related to the public health emergency.

N.J.S.A. § 26:13-18(d) (2008) provides immunity from civil damages for health care providers who are required to assist in the response to the public health emergency, as well as for actions undertaken in pre-event planning, drills or other preparedness activities.

N.J.S.A. § 26:13-19 (2008) contains immunities for private persons or entities, including health care providers, who act in connection with a public health emergency, provided that the “action of the person or entity is undertaken pursuant to the exercise of the authority provided pursuant to [the Emergency Health Powers Act], including any order, rule or regulation adopted pursuant thereto.”

Use of Volunteers

8. N.J.S.A. § 26:13-6 (2008) provides a registration mechanism for volunteer health care workers, public health workers and support services personnel. It also states: “in the event the Governor declares a public health emergency, the commissioner may waive health care facility medical staff privilege requirements for individuals registered as emergency health care workers, and hospitals shall permit registered emergency health care workers to exercise privileges at the hospital for the duration of the public health emergency.”

A. EMERGENCY HEALTH POWERS ACT - QUARANTINE AND ISOLATION

The authority to order the quarantine or isolation of individuals, groups or geographic areas during a public health emergency is an important tool in addressing infectious diseases, especially during the early stages of a pandemic. The Centers for Disease Control and Prevention (CDC) has recognized that quarantine and isolation was an effective tool in the 1918 pandemic. The White House's *National Strategy for Pandemic Influenza Implementation Plan* (2006) recommends the early and aggressive use of social distancing strategies, including quarantine and isolation, in a pandemic. The use of quarantine and isolation, however, raises significant legal and operational concerns for a health care facility; its medical staff and employees; patients; and the larger community. Health care facilities must clearly understand who has the authority to issue quarantine and isolation orders; the scope of persons or areas subject to an order; and the rights to appeal quarantine and isolation orders. Delivering and enforcing quarantine and isolation orders will require the facility to evaluate their rights and responsibilities relative to public health officials and law enforcement. Health care facilities should develop operational protocols for dealing with patients subject to quarantine or isolation. Health care facilities should further evaluate their HR policies and legal obligations to employees required to work with patients or in facilities subject to quarantine or isolation orders.

In your plan, consider the following:

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|------------------------------------|--|-----------|-------------|-------------|----------------------|-------------------|
| AUTHORITY FOR Q/I AND SCOPE | | | | | | |
| 1 | Locate the state's quarantine and isolation (Q/I) laws, which may be found in various places such as the Emergency Health Powers Act; a communicable disease statute or section; or in a stand-alone code section. | | | | | |

A. EMERGENCY HEALTH POWERS ACT - QUARANTINE AND ISOLATION CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|---|-----------|-------------|-------------|----------------------|-------------------|
| 2 | Determine how the Q/I laws interact with the State Emergency Health Powers Act and State Emergency Services Act regarding the restriction of health care workers who have been or may have been exposed to an infectious disease. | | | | | |
| 3 | Identify who has the authority (e.g., governor and/or SHO) to issue an order of Q/I for an individual. | | | | | |
| 4 | Identify if Q/I orders have to be issued only for individuals, or if they can be for groups of individuals. | | | | | |
| 5 | If Q/I orders can be for groups of individuals, determine how the groups are defined. | | | | | |
| 6 | Identify the bases or grounds on which an individual or group can be quarantined or isolated. | | | | | |
| 7 | Determine if a health care facility can be quarantined, which means that no one can enter or leave the premises for the duration of the quarantine. | | | | | |

A. EMERGENCY HEALTH POWERS ACT - QUARANTINE AND ISOLATION CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|-------------------------------|---|-----------|-------------|-------------|----------------------|-------------------|
| 8 | If a health care facility can be quarantined, identify on what grounds and for how long. | | | | | |
| 9 | Identify the process for obtaining an order of Q/I to ensure that the order has been issued properly. | | | | | |
| DELIVERY OF Q/I ORDERS | | | | | | |
| 10 | Identify the process for serving or delivering the Q/I order on an individual. | | | | | |
| 11 | If the person to be served the Q/I order is a health care facility inpatient, determine how the Q/I order will be delivered to the patient. | | | | | |
| 12 | If the Q/I order must be served on the patient to be effective, determine if law enforcement officers or others serving Q/I orders plan to use appropriate personal protective equipment (PPE) to mitigate the server's potential risk of exposure. If not, establish PPE protocols for officials serving orders in the health care facility. | | | | | |

A. EMERGENCY HEALTH POWERS ACT - QUARANTINE AND ISOLATION CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|----------------------------------|---|-----------|-------------|-------------|----------------------|-------------------|
| 13 | Determine if public health agencies will attempt to deputize health care facility workers to deliver Q/I orders on patients; evaluate how this will impact the ability to deliver care. | | | | | |
| ENFORCEMENT OF Q/I ORDERS | | | | | | |
| 14 | Identify the state statute(s) addressing the process for enforcing Q/I orders. | | | | | |
| 15 | Determine who has the authority to enforce the Q/I order, and who is expected to enforce the order. | | | | | |
| 16 | Determine if the health care facility has the legal authority to enforce the order of Q/I by detaining the patient if he/she tries to leave. | | | | | |
| 17 | If the health care facility does not have the authority to detain a patient who is subject to the Q/I order, identify if law enforcement or someone else with such authority will remain with the Q/I patient at all times. | | | | | |

A. EMERGENCY HEALTH POWERS ACT - QUARANTINE AND ISOLATION CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|----|---|-----------|-------------|-------------|----------------------|-------------------|
| 18 | Determine if the health care facility is expected to notify law enforcement or public health officials if the Q/I patient leaves the health care facility. | | | | | |
| 19 | Determine if it is considered malpractice not to enforce a Q/I order and, if so, whether this action would be covered under a professional liability insurance policy. | | | | | |
| 20 | If a public health official directs a health care facility to enforce Q/I orders and prevent the departure of infected individuals, and a health care facility fails to do so, determine if the health care facility will be liable for anyone who becomes sick as a result and how causation will be proved. | | | | | |
| 21 | If a patient must be detained in isolation due to an infectious condition, identify who is responsible for assuring that the patient does not leave isolation. | | | | | |

A. EMERGENCY HEALTH POWERS ACT - QUARANTINE AND ISOLATION CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|--|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 22 | Should some physical force be necessary to assure that a patient in isolation does not leave the isolation facility, determine who, if anyone, will be responsible for physically restraining the isolated patient to prevent them from leaving. | | | | | |
| 23 | Determine if there will be sufficient numbers of law enforcement officials to physically prevent isolated patients from leaving. | | | | | |
| 24 | Identify if there are any liability protections for those who enforce orders of Q/I, including health care facility personnel if they are permitted or expected to do so. | | | | | |
| LEGAL REQUIREMENTS TO HOST PERSONS UNDER Q/I | | | | | | |
| 25 | Determine whether the state law grants the governor or SHO the power to compel health care facilities to shelter a person under Q/I. | | | | | |

A. EMERGENCY HEALTH POWERS ACT - QUARANTINE AND ISOLATION CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---------------------------------|---|-----------|-------------|-------------|----------------------|-------------------|
| 26 | If a health care facility must give shelter to a person under Q/I, identify if a distinction is made between a patient who presented to the health care facility for treatment, or who became a patient solely under the authority of the order of Q/I. | | | | | |
| THIRD PARTY PAYER ISSUES | | | | | | |
| 27 | If a person is in the health care facility solely as a result of a Q/I order, determine whether a third party payer will deny payment because the care arises from a court order and not a health care provider's determination of medical necessity. | | | | | |
| 28 | If a third party payer will not cover the cost of care for a person in the health care facility solely as a result of a Q/I order, determine who will be responsible for payment. | | | | | |

A. EMERGENCY HEALTH POWERS ACT - QUARANTINE AND ISOLATION CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|------------------------------|--|-----------|-------------|-------------|----------------------|-------------------|
| 29 | If a person is in the health care facility solely as a result of a Q/I order, determine whether a third party payer will suspend case management processes. | | | | | |
| APPEALING A Q/I ORDER | | | | | | |
| 30 | Understand that persons subject to Q/I orders generally have the right to a hearing before a court, either before or after imposition of the order. | | | | | |
| 31 | Identify the process for appealing an order of Q/I should the order cover the health care facility's employees, medical staff, or members of key departments and the health care facility wants to challenge or modify the order to allow the person(s) to continue to work. | | | | | |

A. EMERGENCY HEALTH POWERS ACT - QUARANTINE AND ISOLATION CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|----|---|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 32 | <p>If the person appealing the Q/I order is a patient in a health care facility, determine what the courts and public health officials expect health care facilities to provide in these situations.</p> <p>Assess whether these expectations are consistent with the capabilities of the health care facility.</p> | | | | | |
| 33 | <p>Identify whether the health care facility has any right to appeal an order to house a person solely because they are subject to a Q/I order.</p> | | | | | |

A. EMERGENCY HEALTH POWERS ACT - QUARANTINE AND ISOLATION CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|--|---|-----------|-------------|-------------|----------------------|-------------------|
| DUTY TO NOTIFY PUBLIC HEALTH OFFICIALS | | | | | | |
| 34 | Identify what, if any, duties—statutory, regulatory or otherwise—the health care facility has to notify public health officials about potential threats and recommend Q/I for patients or staff. | | | | | |
| 35 | If the health care facility does not notify public health officials regarding patients or staff who may need Q/I, assess whether the health care facility is exposing itself to potential liability. | | | | | |
| HEALTH CARE FACILITY AUTHORITY TO ISSUE Q/I ORDERS FOR PATIENTS | | | | | | |
| 36 | Identify if the health care facility has the authority to issue an order of Q/I for patients to prevent them from leaving the health care facility premises or the health care facility isolation area. | | | | | |
| 37 | If a health care facility is authorized to issue a Q/I order for a patient, determine under what circumstances such an order is permitted and the legal process required to obtain and enforce the Q/I order. | | | | | |

A. EMERGENCY HEALTH POWERS ACT - QUARANTINE AND ISOLATION CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|---|-----------|-------------|-------------|----------------------|-------------------|
| HEALTH CARE FACILITY AUTHORITY TO ISSUE Q/I ORDERS FOR STAFF | | | | | | |
| 38 | Identify if the health care facility has the authority to issue an order of Q/I to prevent a staff person from leaving the health care facility premises or the facility's isolation area if the health care facility determines that the staff member has been exposed to the virus. | | | | | |
| 39 | If a health care facility is authorized to issue a Q/I order for staff, determine who will issue such an order; under what circumstances such an order is permitted; and the legal process required for obtaining and enforcing the Q/I order. | | | | | |
| WORK QUARANTINES | | | | | | |
| 40 | Identify if the health care facility is authorized to issue "work quarantines" restrictions (like those used in the Toronto SARS epidemic) in which staff are prohibited from going any place other than work and home. | | | | | |

A. EMERGENCY HEALTH POWERS ACT - QUARANTINE AND ISOLATION CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|----|---|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 41 | Determine if there are any laws that would inform work quarantine restrictions or would this be considered a health care facility policy. | | | | | |
| 42 | Determine if a health care facility can require that an employee observe work quarantine restrictions, and how such restrictions will be enforced. | | | | | |
| 43 | If a health care facility can use work quarantine, determine if the health care facility is required to provide employees with essential goods (e.g., groceries) that they cannot get because they are not allowed to leave the house except to go to work. | | | | | |
| 44 | Determine how the employee will be compensated for the period they are under a work quarantine restriction. | | | | | |

A. EMERGENCY HEALTH POWERS ACT - QUARANTINE AND ISOLATION CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|--|---|-----------|-------------|-------------|----------------------|-------------------|
| 45 | <p>If a health care facility can issue orders of quarantine or work quarantine restrictions for employees, assess whether these orders or policies expose the health care facility to liability for:</p> <ul style="list-style-type: none"> • Lost wages • Defamation (damage to reputation from being under quarantine) • Intentional infliction of emotional distress (to force employee to stay at home with family, not knowing if they are sick or can give illness to family, may be emotionally trying) | | | | | |
| FEDERAL QUARANTINE AUTHORITY AND AREAS OUTSIDE OF STATE CONTROL | | | | | | |
| 46 | <p>Understand the scope of federal quarantine authority and how it might affect the health care facility.</p> | | | | | |
| 47 | <p>Identify if there are any areas of the state in which the governor, SHO or public health officials would not have the authority to issue an order of Q/I (e.g., military base, federal ports, tribal lands, diplomatic compounds).</p> | | | | | |

A. EMERGENCY HEALTH POWERS ACT - QUARANTINE AND ISOLATION CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|----|--|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 48 | Determine if persons who leave areas outside of state control become subject to Q/I orders issued by state or local officials once they enter an area under state control (e.g., leaving a military base). | | | | | |
| 49 | Determine if there are any agreements or Memoranda of Understanding (MOUs) that permit state or local officials to issue or serve Q/I orders on persons in areas outside of state control. | | | | | |

EMERGENCY HEALTH POWERS ACT - QUARANTINE AND ISOLATION

NEW JERSEY EXAMPLES

Authority for Q/I and Scope

1. Laws related to Q/I during a “state of public health emergency” can be found at N.J.S.A. § 26:13-15 (2008). The general provisions for communicable disease give the Department of Health and Senior Services and the local boards of health the power to “maintain and enforce proper and sufficient quarantine, wherever deemed necessary” (N.J.S.A. § 26:4-2 et seq. (2008)). Finally, there are various quarantine provisions related to incoming vessels (N.J.S.A. § 26:4-101 et seq. (2008)). See also Communicable Disease regulations at N.J.A.C. § 8:57-1.1 et seq.

See also the *New Jersey Influenza Pandemic Plan* (June 2008), Section VII.H. “Community Disease Control and Prevention” which addresses the state’s plan for using quarantine and isolation, as well as other community disease control measures (available at: http://www.state.nj.us/health/flu/panflu_plan.shtml).

2. In New Jersey, the most relevant Q/I laws are part of the New Jersey Emergency Health Powers Act. The interaction between the New Jersey Emergency Health Powers Act and the Civilian Defense Act and Disaster Control Act (N.J.S.A. § App.A.9:33 et seq. (2008)) is discussed above. Outside of the Emergency Health Powers Act, the Department of Health and Senior Services and the local boards of health have the power to “maintain and enforce proper and sufficient quarantine, wherever deemed necessary,” but “in the event the Governor declares a public health emergency, the department shall oversee the uniform exercise of these powers in the state and the local board of health shall be subject to the department’s exercise of authority under this section” (N.J.S.A. § 26:4-2 (2008)).

In some cases, when a need to Q/I an individual arises, it will be in the context of a public health emergency under the State Emergency Health Powers Act or a declared emergency under the State Emergency Services Act. To the extent that the Q/I provisions are separate and apart from these two acts, it is important to understand how they will interact and potentially impact the Q/I process.

3. In New Jersey, during a state of public health emergency, the commissioner of NJDHSS may “issue and enforce orders for the isolation or quarantine of individuals subject to the procedures specified in this section” (N.J.S.A. § 26:13-15(a)(2) (2008)). The commissioner may either issue or seek issuance of an order of Q/I for an individual or a group of individuals, identified by name or shared characteristics (N.J.S.A. § 26:13-15(e)(2)(a) (2008)).

4. The commissioner may either issue or seek issuance of an order of Q/I for an individual or a group of individuals, identified by name(s) or shared characteristics that give rise to the order (N.J.S.A. § 26:13-15(e)(2)(a) (2008)). The commissioner is authorized to use other means to notify individuals or groups subject to a Q/I order if the commissioner determines that individual notice is impractical because of the “number of persons or geographical areas affected,” which suggests that persons within certain geographic parameters can be subject to a group Q/I order (N.J.S.A. § 26:13-15(e)(4)(g) (2008)).
6. In New Jersey, persons can be quarantined or isolated only “if it is determined by a preponderance of the evidence that the person to be isolated or quarantined poses a risk of transmitting an infectious disease to others. A person’s refusal to accept medical examination, vaccination, or treatment pursuant to section 13 or 14 of this [Emergency Health Powers Act] shall constitute *prima facie* evidence that the person should be quarantined or isolated” (N.J.S.A. § 26:13-15(b)(1) (2008)). The state also has authority to subject a person who believes in prayer healing to all rules and regulations for quarantine and isolation in cases of contagious or infectious diseases (N.J.S.A. § 30:4A-12 (2008)).
7. In New Jersey, the Q/I statute does not specifically say that a facility can be quarantined. It speaks primarily in terms of persons. The statute does, however, empower the commissioner to “designate, including an individual’s home when appropriate, and establish and maintain suitable places of isolation and quarantine” (N.J.S.A. § 26:13-15(a)(1) (2008)). Furthermore, “no person, other than a person authorized by the commissioner, may enter the isolation or quarantine premises. Any person entering an isolation or quarantine premises may be isolated or quarantined” (N.J.S.A. § 26:13-15(d)(2) (2008)). In practice then, if the commissioner designates an area as a suitable place for isolation or quarantine, he/she has effectively “quarantined” it in that no one can enter or leave the premises without special permission from the commissioner.
9. The process for issuing a Q/I order is found in N.J.S.A. § 26:13-15(e) (2008). Subsection (e)(3) provides that “before isolating or quarantining a person, the commissioner shall obtain a written order, which may be an *ex parte* order, from the Superior Court authorizing such action.” Subsection (e)(4) allows the commissioner to “issue a verbal order, to be followed by a written order requiring the immediate, temporary isolation or quarantine of a person or group of person...without first obtaining an order from the court if the commissioner determines that any delay in the isolation or quarantine of the person would significantly jeopardize the ability to prevent or limit the transmission of infectious or possibly infectious disease to others.” State regulations authorize local health officers or the department to issue an isolation order upon receiving a report of a communicable disease. The health officers or the department is authorized to move a person who is ill with a communicable disease to a hospital (see N.J.A.C § 8:57-1.9 (2008)).

Subsection (e) also specifies the content of orders of Q/I which includes the identity of the subject of the order; the premises designated for isolation or quarantine; the date and time at which the isolation or quarantine commences; the suspected contagious disease (if known); the terms and conditions of the isolation or quarantine; a statement of the basis upon which the isolation or quarantine is justified; and a “statement of what effort, if any, has been made to give notice of the hearing to the person or group of persons to be isolated or quarantined, or the reason supporting the claim that notice should not be required” (N.J.S.A. § 26:13-15(e)(2) (2008)). When the commissioner issues a verbal order, and then a written order, the written order has to contain all of the same elements listed above, except instead of the statement of the effort to give notice, the order must specify “the availability of a hearing to contest the order” (N.J.S.A. § 26:13-15(e)(4) (2008)). This deserves further discussion with the department.

As part of its advanced planning for pandemic influenza, the department has created template orders for voluntary and involuntary Q/I orders (see *New Jersey Influenza Pandemic Plan* (June 2008), Section VII.H “Community Disease Control and Prevention” available at: http://www.state.nj.us/health/flu/documents/plan/comm_app_2.pdf).

Delivery of Q/I Orders

10. The New Jersey statute does provide that “a copy of the authorizing order shall be provided to the person ordered to be isolated or quarantined, along with notification that the person has a right to a hearing pursuant to paragraph (5) of this subsection” (N.J.S.A. § 26:13-15(e)(3) (2008)). If the commissioner issues a verbal order followed by a written order, as discussed above, then the commissioner should provide notice of the order to the person or persons specified in the order (N.J.S.A. § 26:13-15(e)(4) (2008)). If, however, it is “impractical because of the number of persons or geographical areas affected, or other good cause” to provide notice to each person, then he/she can use the “best possible means available” to ensure that all affected persons are notified (N.J.S.A. § 26:13-15(e)(4) (2008)). He/she should also post a copy of the order “in a conspicuous place in the isolation or quarantine premises” (N.J.S.A. § 26:13-15(e)(4) (2008)). It is possible that those serving orders of isolation or quarantine may be themselves quarantined under N.J.S.A. § 26:13-15(d)(2) or (e)(4) (2008).

Once an order of Q/I is issued, it typically has to be served to the individual subject to the order. Once a mass disease event occurs in a community, travel may be restricted. In Toronto in 2003, workers, patients and others at hospitals affected by SARS were not permitted to leave the hospital because they could have infected the larger community if they had done so.

Enforcement of Q/I Orders

14. Under the New Jersey Emergency Health Powers Act, of which the Q/I statutes are a part, “the commissioner shall have the power to enforce the provisions of this act through the issuance of orders and such other remedies as are provided by law” (N.J.S.A. § 26:13-27 (2008)). More specifically, the Q/I statute gives the commissioner the power to enforce orders for the isolation and quarantine of individuals (N.J.S.A. § 26:13-15(a)(2) (2008)). The statute does not provide any further guidance on the enforcement mechanisms for orders of Q/I. State regulations require that persons responsible for the “care, custody, or control of a person who is ill or infected with a communicable disease shall take all measures necessary to prevent transmission of the disease to other persons” (N.J.A.C. § 8:57-1.9(d) (2008)); however, the regulation does not address specific enforcement measures.

There are no specific immunity provisions related to the enforcement of orders of Q/I. There are, however, various immunity provisions related to injuries caused by acts or omissions in connection with a public health emergency, “provided that the action...is undertaken pursuant to the exercise of the authority provided pursuant to this act, including any order, rule or regulation adopted thereto” and for the rendering of assistance to a public entity or public employee in connection with the public health emergency (N.J.S.A. § 26:13-19(c) (2008)). These provisions may be construed to provide protection to the extent that the health care facility is required to help enforce orders of Q/I.

Once an order of Q/I is issued, it then has to be enforced. This raises a host of issues in and of itself, but raises even more issues if the individual is quarantined or isolated in the health care facility. The health care facility must understand its obligations, if any, to enforce the order and the parameters around this obligation. To the extent that the health care facility bears this obligation, it must also understand its liability for either performing or failing to perform these tasks. The existing laws do not address this specifically.

Legal Requirements to Host Persons under Q/I

25. In New Jersey, the commissioner may have the power to require a hospital to shelter a person who is subject to quarantine or isolation. Specifically, the statute says that the commissioner has the power to “designate...and establish and maintain suitable places of isolation and quarantine” (N.J.S.A. § 26:13-15(a)(1) (2008)). Notably, it does not say that he has the power to designate a hospital as the quarantine or isolation premise, nor does it say that he is prohibited from doing so. This statute should also be read in the context of the Emergency Health Powers Act, which gives the commissioner the ability to take over control of a hospital, as discussed in Section A - Commandeering and Closure. Health care facilities should ask the department to clarify its thinking on this issue.

Appealing a Q/I Order

30. The commissioner must seek a written Q/I order – which may be *ex parte* – from the Superior Court authorizing the order (N.J.S.A. § 26:13-15(e)(g)(3) (2008)). “The court shall grant a hearing within 72 hours of the filing of a petition when a person has been isolated or quarantined pursuant to paragraph (3) or (4) of this subsection” (N.J.S.A. § 26:13-15(e)(5)(g) (2008)). “The court may extend the time for hearing upon a showing by the commissioner that extraordinary circumstances exist that justify the extension” (N.J.S.A. § 26:13-15(e)(5)(g) (2008)). In contrast to other provisions of this section, this appeal provision does not appear to exclude Saturdays, Sundays and legal holidays. Presumably, this means that the petition must be heard within 72 hours of filing. The statute does not define what constitutes “extraordinary circumstances” for purposes of justifying an extension. Finally, it is unclear whether a petition stays the order because it is not explicitly mentioned in subsection (5)(g) as it is in other subsections that address appeal rights (see, for example, (5)(f) discussed below). It is likely that an order being appealed under (5)(g) would not be stayed pending the appeal.

Following the hearing described above, between the 10th and 21st day of isolation or quarantine, the individual subject to the order can request a court hearing to contest his/her continued isolation or quarantine (N.J.S.A. § 26:13-15(f) (2008)). This hearing must be held within 72 hours of receipt of the request, excluding weekends and holidays, and specifically does not stay the order. Finally, at any time during the period of isolation or quarantine, the individual may request a hearing in the Superior Court for “injunctive relief regarding his/her treatment and the terms and conditions of the quarantine or isolation” (N.J.S.A. § 26:13-15(f)(2) (2008)). This hearing must be held no later than 10 days after receipt of the request and does not stay the order.

Duty to Notify Public Health Officials

34. The New Jersey Emergency Health Powers Act requires health care providers (which includes health care facilities) to report to the department and local health officials all cases of persons who “harbor or are suspected of harboring any illness or health condition that may reasonably be potential causes of a public health emergency” (N.J.S.A. § 26:13-4(b) (2008)). Illnesses and health conditions include, but are not limited to, any illness or health conditions identified by the commissioner. Pharmacists are required to report unusual increases in the types of prescriptions used to treat the conditions identified by the commissioner; antibiotics; or medicines used to treat uncommon diseases or those related to acts of terrorism (N.J.S.A. § 26:13-4(c) (2008)).

The commissioner will specify the frequency and types of reports required (N.J.S.A. § 26:13-4(d) (2008)). New Jersey's *Influenza Pandemic Plan* (June 2008) includes plans for conducting heightened surveillance activities for influenza linked to phases of an influenza pandemic outbreak. The plan is available at: http://www.state.nj.us/health/flu/panflu_plan.shtml. The plan notes that:

“The World Health Organization (WHO) has created six phases of increased public health risk associated with an influenza virus having the potential to cause a pandemic. In addition to the pandemic phases, the federal government developed six response stages for a pandemic, with each stage requiring governmental actions.

The NJ State Pandemic Influenza Response Plan has ten situations that trigger responses within NJ's critical infrastructure sectors. The NJDHSS Operations Plan further divides these situations by adding five situations that are geographically NJ specific, and two situations described as 'increased and sustained transmission in the general population' and 'between waves.' As the situations change, NJDHSS notifies internal and external partners" (*New Jersey Influenza Pandemic Plan*, Section V. "Strategy").

Therefore, health care providers will be notified when to commence heightened surveillance activities and the associated reporting criteria.

Additionally, pursuant to New Jersey's communicable disease laws, physicians, hospitals and other facilities have a legal duty to report cases of communicable diseases. Physicians must report within 12 hours after the diagnosis that a person is ill or infected with a communicable disease or other disease required to be reported (N.J.S.A. § 26:4-15 (2008)). The physician must report the diagnosis and any information as may be required by the State Department of Health. The report must be in writing and include the name of the reporting physician, the name of the disease, the name, age and precise location of the person ill or infected with the disease and such other information as may be required by regulation of the State Department of Health (N.J.S.A. § 26:4-15 (2008)). Hospitals and other facilities required to report within 24 hours include "[e]very physician, superintendent or other person having control or supervision over a state, county or municipal health care facility, sanatorium or other public or private institution" (N.J.S.A. § 26:4-19 (2008)). The state also has a law that requires "[e]very house owner or householder who has reason to believe that any person living, dwelling or being in any building under his control is ill or infected with any disease required by law or the State Sanitary Code to be reported shall, when no physician has professionally attended the ill or infected person, within 12 hours after discovering the same, report the fact in person, by telephone or in writing to the health officer or other officer or employee designated to receive such reports by the local board of health having jurisdiction of the area" (N.J.S.A. § 26:4-16 (2008)). The list of reportable diseases is contained at N.J.A.C. § 8:57-1.3 (2008); however, the list does not include influenza viruses, but broadly covers "any outbreak or suspected outbreak."

Health Care Facility Authority to Issue Q/I Orders for Patients

36. The New Jersey Emergency Health Powers Act does not address whether a health care facility has the authority to unilaterally issue an order of quarantine or isolation that would be enforceable. A health care facility does have the ability to place a patient in an isolation room, although it does not have the ability to hold the patient there against his will.

Health Care Facility Authority to Issue Q/I Orders for Staff

38. Under the New Jersey Emergency Health Powers Act, there are no provisions that would give the health care facility the authority to unilaterally issue a "work quarantine" order. The commissioner could potentially issue a "work quarantine" order by describing the "work quarantine" in the terms and conditions section of the order.

It may be prudent to speak with the department about its thoughts on this issue if the health care facility believes that work quarantine orders would be desirable during a pandemic. The New Jersey Emergency Health Powers Act does address reinstatement of employment after isolation and quarantine in N.J.S.A. § 26:13-16 (2008), but this relates to orders issued by the commissioner, not a private entity.

Health care facilities may want to issue orders of quarantine for its staff, especially “work quarantines” like those used in the Toronto SARS epidemic. During a “work quarantine,” staff are prohibited from going any place other than work and home.

Federal Quarantine and Areas Outside of State Control

46. Under the U.S. Public Health Service Act, the U.S. DHHS is authorized to prevent the entry and spread of communicable diseases from foreign countries through ports of entry into the United States and between states (42 U.S.C. § 264 (2008)). Although protecting the public’s health and welfare is a power reserved to the states, the federal government’s isolation and quarantine authority is derived from the Commerce Clause of the U.S. Constitution. The CDC is authorized under 42 CFR Parts 70 and 71 to detain, medically examine and release persons arriving into the United States and traveling between states who are suspected of carrying communicable diseases. The federal government is authorized to accept assistance from state and local governments in enforcing federal quarantine orders. The federal government may also assist state and local governments in preventing the spread of communicable diseases. State, local and tribal governments are responsible for enforcing isolation and quarantine orders within their borders. It is possible for federal, state, local and tribal health authorities to simultaneously have and use separate but coexisting legal quarantine power in certain events. In the event of a conflict, federal law governs.

The federal government has rarely used its quarantine authority; however, during a pandemic or other declared public health emergency, it is likely that federal quarantine authority will be used more frequently to manage the event.

47. In many states, there are areas of the state that are under the jurisdiction of tribal or federal government; therefore, state laws do not apply. As a result, the commissioner does not have the power to issue orders of Q/I for individuals in these areas. To the extent that individuals leave these areas and enter areas controlled by the state, however, the commissioner can serve them with orders of Q/I. States generally enter into MOUs and other agreements with federally controlled properties within their boundaries to cooperate in the execution of public health and law enforcement orders.

B. EMERGENCY SERVICES LAW - INITIAL PLANNING

Each state has a set of statutes that grant the governor the authority to declare a state of emergency or a disaster when circumstances warrant. After declaring a disaster or emergency, the governor – and potentially others within the state’s executive branch – is vested with additional responsibilities, rights and powers that will allow him/her to respond to the disaster most effectively and efficiently. In many states, these statutes are collectively referred to as the Emergency Services Act. In some states, however, this is not the case. For example, the New Jersey Emergency Services Act of 1972 (N.J.S.A. § 52:14E-1 et seq. (2008)) describes the authority of the Governor’s Advisory Council for Emergency Services and the use of the Emergency Services Fund; however, the Civilian Defense Act and Disaster Control Act (N.J.S.A. § App.A:9-33 et seq. (2008)) contains the statutes related to the governor’s authority to declare an emergency and the powers that flow from such a declaration.

In your plan, consider the following:

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|------------------------------|--|-----------|-------------|-------------|----------------------|-------------------|
| EMERGENCY DECLARATION | | | | | | |
| 1 | Identify and review the state’s Emergency Services Act. | | | | | |
| 2 | Identify whether a pandemic can be declared an “emergency” under the Emergency Services Act. | | | | | |
| 3 | Identify who under state law has the power to declare an emergency. | | | | | |
| 4 | Identify the mechanisms for and pre-requisites to declaring an emergency. | | | | | |

B. EMERGENCY SERVICES LAW - INITIAL PLANNING CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---------------------------|--|-----------|-------------|-------------|----------------------|-------------------|
| 5 | Determine how the health care facility will know that a declaration has been issued and obtain a copy of the document. | | | | | |
| 6 | Identify all provisions of the Emergency Services Act that may impact the health care facility. | | | | | |
| 7 | Understand the processes and procedures that are in place for a health care facility to respond to the governor's exercise of power under the Emergency Services Act. | | | | | |
| SUSPENSION OF LAWS | | | | | | |
| 8 | Identify if the Emergency Services Act gives the governor the authority to suspend laws and regulations. | | | | | |
| 9 | Identify what state laws or regulations the health care facility would have difficulty complying with during an emergency. See all other sections of the Legal module. | | | | | |

B. EMERGENCY SERVICES LAW - INITIAL PLANNING CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|------------------------------------|--|-----------|-------------|-------------|----------------------|-------------------|
| 10 | Seek to include those suspension provisions into draft emergency declarations that are being prepared for the governor. | | | | | |
| INTERACTION WITH OTHER LAWS | | | | | | |
| 11 | Identify how the Emergency Services Act interacts with the Emergency Health Powers Act. | | | | | |
| 12 | Identify how the Emergency Services Act interacts with any quarantine and isolation laws. | | | | | |
| 13 | Determine if other persons or agencies are granted additional rights and powers as a result of the declaration that could impact the health care facility. | | | | | |

EMERGENCY SERVICES LAW - INITIAL PLANNING

NEW JERSEY EXAMPLES

The *New Jersey Influenza Pandemic Plan* (June 2008), Section VII.C. "Health Care Planning" includes information about the state's plans for addressing obstacles to health care planning, including command and control of health care resources and the waiver of state regulations (available at: http://www.state.nj.us/health/flu/panflu_plan.shtml).

Emergency Declaration

1. The New Jersey Emergency Services Act is located at N.J.S.A. § App.A:9-33 et seq. (2008).

See also the *New Jersey Influenza Pandemic Plan*, which summarizes the state's legal authorities during a pandemic in Section II. "Authorities" and Section IV. "Planning Assumptions," addressing in part how those powers will be used (available at: http://www.state.nj.us/health/flu/panflu_plan.shtml).

2. Pursuant to N.J.S.A. § App. A:9-33.1 (2008), a "disaster shall mean any unusual incident resulting from natural or unnatural causes which endangers the health, safety or resources of the residents of one or more municipalities of the state, and which is or may become too large in scope or unusual in type of be handled in its entirety by regular municipal operating services." Under this same statute, an "emergency" includes a "disaster." A pandemic caused by an influenza virus can be both a disaster and an emergency.

3. N.J.S.A. § App. A: 9-40.5 (2008) grants the municipal emergency management coordinator the ability to proclaim a state of local disaster or emergency within his/her municipality. Under N.J.S.A. § App. A: 9-51 (2008), the governor has the authority to proclaim an emergency.

4. The municipal emergency management coordinator can proclaim a state of local disaster or emergency when a disaster has occurred or is imminent in his/her municipality (N.J.S.A. § App. A: 9-40.5 (2008)). The governor can proclaim an emergency when, "in his/her opinion, the control of any disaster is beyond the capabilities of local authorities" (N.J.S.A. § App. A: 9-51 (2008)).

6. Neither N.J.S.A. § 52:14E-1 et seq. (2008) or N.J.S.A. § App. A: 9-30 et seq. (2008) address specific processes and procedures in place for a health care facility to respond to the governor's exercise of power under these statutes.

Suspension of Laws

8. The governor may suspend regulatory provisions of law, the enforcement of which would be detrimental to the public welfare during preparations for emergencies, or the threat or imminence of danger in an emergency (N.J.S.A. § App. A: 9-47 (2008)). Furthermore, the governor has the power to make orders, rules and regulations that are necessary to meet the various problems presented by any emergency (N.J.S.A. § App. A: 9-45 (2008)).

9. N.J.S.A. § App. A:9-45 (2008) gives the governor the authority to make such orders, rules and regulations as he/she deems necessary in an emergency, including those concerning the organization, recruiting, training, conduct, duties and powers of volunteer agencies including medical corps and nurses' aids corps. The governor also has the ability to suspend certain regulations (N.J.S.A. § App. A: 9-47 (2008)). Together, these statutes may be construed as giving the governor the authority to license out-of-state or retired health care providers during a pandemic. The governor should be consulted on whether the needed regulatory suspensions would be forthcoming during a pandemic.

Interaction with Other Laws

11. See Emergency Health Powers Act, Section A of the Legal module.

12. See Emergency Health Powers Act, Section A of the Legal module.

13. The municipal emergency management coordinator, in accordance with regulations promulgated by the state director of emergency management, has authority to issue and enforce orders to "carry out emergency management operations and to protect the health, safety and resources of the residents of the municipality" (N.J.S.A. § App. A: 9-40.5 (2008)). Such orders could impact health care facilities within the municipality.

B. EMERGENCY SERVICES LAW - CONTROL, USE AND CLOSURE

State emergency management laws may authorize the governor to take control of health care facilities, equipment, medicines and supplies, as well as compel licensed health professionals to report to work during a declared public health emergency. Health care facilities should carefully understand the processes for issuing and appealing such orders, and procedures for re-opening the facility and recouping the value of property taken or used. Health care facilities must develop strategies, such as securing business interruption insurance to mitigate the effects of a closure or confiscation.

In your plan, consider the following:

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|--|---|-----------|-------------|-------------|----------------------|-------------------|
| CLOSURE OF HEALTH CARE FACILITIES | | | | | | |
| 1 | Identify if the governor or another delegated official is permitted to close a health care facility under the Emergency Services Act. | | | | | |
| 2 | Identify if there is a process to appeal closure under the Act and, if so, what is the process for appeal. | | | | | |
| 3 | Identify if an appeal will allow for a stay in the order to close. | | | | | |

B. EMERGENCY SERVICES LAW - CONTROL, USE AND CLOSURE CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|--|--|-----------|-------------|-------------|----------------------|-------------------|
| CONTROL OF PERSONS | | | | | | |
| 4 | Identify if the governor has the authority to require licensed medical professionals to report for work. See Emergency Laws, Emergency Health Powers Act, Section A. of this Legal module. | | | | | |
| CONTROL OF HEALTH CARE FACILITIES | | | | | | |
| 5 | Identify if the governor or another delegated official is permitted to take control of the health care facility under the Emergency Services Act. | | | | | |
| 6 | Identify if there is a process to appeal a governmental decision to assume control of a health care facility under the act. If so, identify the process for appeal. | | | | | |
| 7 | Identify if an appeal will allow for a stay in the governmental order assuming control of a health care facility. | | | | | |
| 8 | Clarify who is responsible for continued operation post-seizure – the health care facility's current management or the government. | | | | | |

B. EMERGENCY SERVICES LAW - CONTROL, USE AND CLOSURE CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|--|---|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 9 | Clarify that, upon governmental seizure of the health care facility, the organization has no further liability for acts that occur during the period of seizure. | | | | | |
| CONFISCATE SUPPLIES, EQUIPMENT OR MEDICINES | | | | | | |
| 10 | Identify if the governor or another delegated official has authority to confiscate a health care facility's supplies, equipment or medication under the Emergency Services Act. | | | | | |
| 11 | Identify if there is a process to appeal a governmental order to confiscate a health care facility's supplies, equipment or medication under the act. If so, identify the process for appeal. | | | | | |
| 12 | Identify if an appeal will allow for a stay in the governmental order to confiscate a health care facility's supplies, equipment or medication. | | | | | |

B. EMERGENCY SERVICES LAW - CONTROL, USE AND CLOSURE CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|------------------------------------|--|-----------|-------------|-------------|----------------------|-------------------|
| MITIGATION AND COMPENSATION | | | | | | |
| 13 | Determine if there is any mechanism for cooperation if a health care facility is closed or commandeered. | | | | | |
| 14 | Determine if the health care facility has business interruption insurance and, if so, the extent of coverage and policy limits. See Contract Issues, Third Party Reimbursement, Section H of this Legal module. | | | | | |
| 15 | Determine the process for regaining control or re-opening the health care facility after a pandemic. | | | | | |
| 16 | If the governor has the ability to commandeer the health care facility and/or its supplies, or require people to report to work, identify the compensation that is available to the health care facility or employees. | | | | | |

EMERGENCY SERVICES LAW - CONTROL, USE AND CLOSURE

NEW JERSEY EXAMPLES

1. The New Jersey Emergency Services Law (N.J.S.A. § App. A: 9-34 (2008)) gives the governor the authority to commandeer and utilize any personal services and any privately owned property necessary to avoid or protect against any emergency subject to reasonable compensation. N.J.S.A. § App. A: 9-51 (2008) gives the governor the authority to take or use the personal services or property of any person or business in New Jersey to promote the public health, safety or welfare when control of any disaster is beyond the capabilities of a local authority. Compensation must be provided for the taken services and property. Read together, these provisions give the governor the authority to use the property of a health care facility and require that those within the facility (management, clinical and otherwise) continue to provide services.

See also the *New Jersey Influenza Pandemic Plan* (June 2008), Section VII.C. "Health Care Planning" which includes information about the state's plans for addressing obstacles to health care planning, including command and control of health care resources and the waiver of state regulations (available at: http://www.state.nj.us/health/flu/panflu_plan.shtml).

4. Although New Jersey law does not explicitly address the governor's authority to require licensed medical professionals to report to work, the governor does have the power to employ temporarily, take or use the personal services of a citizen for the purpose of securing the defense of the state or of protecting or promoting the public health, safety or welfare (N.J.S.A. §§ App. A:9-34 and 9-51 (2008)).

10. Presumably, under the authority cited, the Governor could commandeer a health care facility's property, including supplies, equipment and medication, during an emergency (N.J.S.A. §§ App. A:9-34 and 9-51 (2008)).

16. If the Governor exercises his power to commandeer property or require personal services, business and persons subject to these orders are entitled to compensation in accordance with the procedures outlined in N.J.S.A. § App. A:9-51(c) (2008). With respect to personal services, compensation "shall be paid at the prevailing established rate for services of a like or similar nature" (N.J.S.A. § App. A:9-51 (2008)).

B. EMERGENCY SERVICES LAW - PROVIDING CARE AND VOLUNTEERS

The State Emergency Services Act provides liability protections for health care professionals volunteering in a declared public health emergency. Health care facilities should familiarize themselves with the rights and duties of health care workers during a declared public health emergency. See also Volunteers, Section J in the Legal module.

In your plan, consider the following:

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|---|-----------|-------------|-------------|----------------------|-------------------|
| 1 | Determine whether, and to what extent, the Emergency Services Act provides liability protection for persons providing care in a health care facility during a pandemic. | | | | | |
| 2 | Evaluate whether liability protection is limited to volunteers, licensed providers or any other specific group of persons. | | | | | |
| 3 | Identify any gaps in liability protections and determine if gaps can be addressed by regulation and emergency orders, or if they will require an amendment to the law. | | | | | |
| 4 | Identify whether and to what extent immunity is available for health care facilities giving the government use of their property in responding to the pandemic. | | | | | |

B. EMERGENCY SERVICES LAW - PROVIDING CARE AND VOLUNTEERS CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|---|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 5 | Determine whether the Emergency Services Act allows for out-of-state licensed health care providers to come into the state to provide care in a health care facility. If so, determine the responsibilities of the health care facility regarding tracking and reporting of volunteers' activities. | | | | | |

EMERGENCY SERVICES LAW - PROVIDING CARE AND VOLUNTEERS

NEW JERSEY EXAMPLES

1. The New Jersey Emergency Services Law (N.J.S.A. § App. A: 9-52 (2008)) provides immunity protections.
2. N.J.S.A. § App. A:9-52 (2008) provides immunity for agents or representatives of the state, including all volunteers, who in good faith carry out, comply with or attempt to comply with any order, rule, or regulation promulgated pursuant to N.J.S.A. § App. A: 9-30 et seq. (2008), or who perform authorized services. This statute does not appear to give immunity to private actors like hospitals and health care providers, unless they are acting under direct orders from the governor.
4. N.J.S.A. § App. A:9-52 (2008) protects from civil liability a person owning, possessing or managing any real property which has been designated as a shelter from destructive operations or attacks by enemies of the United States, except to the extent that such liability was caused by the willful acts of the owner, manager or his agents or employees. This section does not define “destructive operations” or “attacks by enemies;” therefore, it is somewhat unclear whether this particular provision applies to all emergencies, or just those involving enemy attacks.

C. FACILITY LICENSURE AND REGULATORY ISSUES - **INITIAL PLANNING**

Health care is heavily regulated at the state and federal level. While health care facilities are well aware of these legal requirements and operate in compliance with numerous regulations every day, many have not thought about how they will operate in compliance with these requirements during a pandemic. Although health care facilities should continue to seek regulatory relief, a basic planning assumption should be that the legal requirements remain in full force and effect, even in the midst of a pandemic.

In your plan, consider the following:

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|---|-----------|-------------|-------------|----------------------|-------------------|
| 1 | Identify any legal provisions that require a health care facility to have an emergency operations plan, including but not limited to Joint Commission requirements. | | | | | |
| 2 | Understand how failure to have a plan or other possible violations of these legal requirements will impact the health care facility's licensure status. | | | | | |
| 3 | Even if not specifically legally mandated, evaluate the liability risk for negligent failure to prepare if the health care facility does not have a comprehensive emergency preparedness and response plan. | | | | | |

C. FACILITY LICENSURE AND REGULATORY ISSUES - INITIAL PLANNING CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|----|--|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 4 | Create a list of those statutes and regulations for licensure or permits with which it may be difficult to comply during an emergency. | | | | | |
| 4a | Identify any legally mandated staffing ratios for hospitals. | | | | | |
| 4b | Identify any legally mandated staffing ratios for non-hospital providers (e.g., long term care, ambulatory surgery center, etc.) within an integrated delivery system. | | | | | |
| 4c | Identify any legal mandates regarding the maximum number of patients in a room. | | | | | |
| 4d | Identify any legal requirements regarding the location of health care facility beds that would otherwise prevent a facility from placing beds in areas that are not patient rooms (e.g., conference rooms, procedure rooms, cafeteria). Consider licensed bed capacity and life safety fire codes. | | | | | |

C. FACILITY LICENSURE AND REGULATORY ISSUES - INITIAL PLANNING CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|----|---|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 4e | Identify any legal requirements regarding services that patients must be offered. | | | | | |
| 4f | Identify regulatory reporting requirements that are considered "routine" in normal times but which could be difficult to do during a pandemic due to severe staffing shortages. | | | | | |
| 5 | Understand how non-compliance with these statutes and regulations during a pandemic will impact the health care facility's ability to continue operations, and how it might expose the facility to administrative fines or penalties or other types of liability. | | | | | |
| 6 | Once the list of statutes and regulations is compiled in accordance with Item 4, determine whether any can be suspended or modified during a pandemic. | | | | | |

C. FACILITY LICENSURE AND REGULATORY ISSUES - INITIAL PLANNING CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|---|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 7 | Begin discussions with the relevant state authorities regarding such regulatory suspensions. See Emergency Health Powers Act and Emergency Services Act, Section A of the Legal module. | | | | | |

FACILITY LICENSURE AND REGULATORY ISSUES - INITIAL PLANNING

NEW JERSEY EXAMPLES

1. N.J.A.C. § 8.43G-5.16(a) (2008) requires hospitals to have a written, comprehensive disaster plan consisting of at least those components listed in the regulation. The Joint Commission also requires that, to be accredited, hospitals have written emergency operations plans that address six critical areas: communication; resources and assets; safety and security; staff responsibilities; utilities management; and patient clinical and support activities (EC.4.11-20).

See also the *New Jersey Influenza Pandemic Plan* (June 2008), Section VII.C. "Health Care Planning" which provides guidance to health care facilities and providers on response plans, communications, patient triage, surge capacity and planning for the provision of health care in non-hospital settings. It also includes information about the state's plans for addressing obstacles to health care planning, including command and control of health care resources and the waiver of state regulations (available at: http://www.state.nj.us/health/flu/panflu_plan.shtml).

4a. The New Jersey hospital licensing regulations contain numerous staffing ratios related to hospital services:

- Cardiac Surgery: N.J.A.C. § 8:43G-7.5(a) (2008).
- Pediatric Cardiac Surgery: N.J.A.C. § 8:43G-7.38(b) (2008).
- Intermediate Care: N.J.A.C. § 8:43G-9.20(a)(6) (2008).
- Trauma Services: N.J.A.C. § 8:43G-12.18(a)(4) (2008).
- Infection Control: N.J.A.C. § 8:43 G-14.5(b) (2008).
- Labor, Delivery, Anesthesia, and Recovery: N.J.A.C. § 8:43G-19.12(b)(7)(ii) (2008).
- Newborn Services: N.J.A.C. § 8:43G-19.16(g) (2008).
- Physical Therapy: N.J.A.C. § 8:43G-29.5 (2008).
- Inpatient Dialysis: N.J.A.C. § 8:43G-30.6(b)-(c) (2008).
- Postanesthesia Care: N.J.A.C. § 8:43G-35.3(b) (2008).

Furthermore, pursuant to N.J.A.C. § 8:43G-17.1(a)(3)(iv) (2008) which addresses staffing, hospitals must have contingency plans to address critical departures from nurse staffing plans, including policies and procedures to regulate closure of available beds if staffing levels fall below specified levels.

4b. The New Jersey regulations also contain staffing ratios and requirements for various non-hospital health care providers, which may be part of an integrated delivery system:

- Cardiac Diagnostic Facilities and Cardiac Surgery Centers: N.J.A.C. § 8: 33E-2.4 (2008).
- Regionalized Perinatal Services and Maternal and Child Health Consortia: N.J.A.C. § 8:33C-7.3 (2008).
- Assisted Living Residences, Personal Care Homes, and Assisted Living Programs: N.J.A.C. § 8:36-9.3 (2008).
- Long Term Care Facilities: N.J.A.C. §§ 8:39-25.1; 8:39-25.2 (2008).
- Home Health Agencies: N.J.A.C. § 8:42-7.3 (2008).
- Hospice: N.J.A.C. §§ 8:42C-7.1; 8:42C-7.3 (2008).
- Residential Health care Facilities: N.J.A.C. §§ 8:43-4.1; 8:43-4.5 (2008).
- Ambulatory Care Facilities: N.J.A.C. §§ 8:43 A-24.17; 8:43A-24.7(c) (2008).
- Pediatric Community Transitional Homes: N.J.A.C. § 8:43D-5.11 (2008).
- Pediatric Day Health Services Facilities: N.J.A.C. § 8:43F-19.2 (2008).
- Rehabilitation Hospitals: N.J.A.C. §§ 8:43H-3.4(d); 8:43H-8.5; 8:43H-8.6; 8:43H-9.1 (2008).

4c. Neither Chapter 43G of the New Jersey Administrative Code, nor Title 26 of the New Jersey Statutes – both of which pertain to licensure of hospitals – contain provisions regarding the number of patients in a room. There is a regulation that requires that the patient have enough space in the patient’s room to store personal belongings (N.J.A.C. § 8:43G-4.1(a)(26) (2008)). Consider that, to the extent a hospital is putting at least two people in an otherwise private room, it should examine the rate at which it will bill the patients (private v. semi-private).

4d. No provisions explicitly prevent the hospital from placing patients in areas of the hospital that are not traditionally used as patient rooms; however, some provisions may indirectly impact the hospital’s ability to relocate certain patients and services. Subchapter 19, which addresses obstetrics, imposes some spatial requirements on the placement of bassinets (e.g., there must be sufficient space between each bassinet) (N.J.A.C. § 8:43G-19.36(b) (2008)). Similarly, subchapter 30, addressing inpatient renal dialysis units, also imposes spatial specifications – at least four feet must separate one bed from another (N.J.A.C. § 8:43G-30.5(b) (2008)). Additionally, subchapter 22, addressing pediatrics, requires that a minimum 10 percent of the beds used for pediatric care are capable of functioning as isolation rooms (N.J.A.C. § 8:43G-22.12(a) (2008)).

4e. In New Jersey, licensure standards require that between October 1 and February 1 of each year, all patients age 65 and over be screened for influenza and, if eligible, offered vaccination against influenza (N.J.A.C. § 8:43G-14.6(a) (2008)). This regulation also requires hospitals to screen all patients age 65 and over for pneumococcal disease and provide them with an opportunity to receive vaccination against this disease (N.J.A.C. § 8:43G-14.6(b) (2008)). While very important, especially during a pandemic, these provisions may present an issue for hospitals if the required vaccines are not available. In addition, N.J.A.C. § 8:43G-2.12(a) (2008) requires hospitals applying for licensure to offer the following mandatory professional departments, services, facilities, and functions:

1. Administration
2. Anesthesia department
3. Blood bank
4. Central supply
5. Clinical and pathological laboratories
6. Dietary services
7. Discharge planning
8. Emergency department
9. Employee and occupational health
10. Electrocardiogram laboratory
11. Housekeeping and laundry services
12. Infection control and sanitation
13. Medical library
14. Medical records
15. Medical/surgical service
16. Medical staff
17. Morgue and autopsy facilities
18. Nursing service
19. Outpatient and preventive services (including regularly scheduled clinic services for medically indigent patients)
20. Pharmacy department
21. Physical and occupational therapy
22. Physical plant and maintenance
23. Post-anesthesia care unit
24. Quality assurance
25. Radiology
26. Respiratory therapy services
27. Social work department

This list of required services, departments and functions may severely limit a health care facility's ability to discontinue services on this list which are not otherwise critical to its operations during an emergency.

5. Pursuant to N.J.S.A. § 26:2H-5g(e) (2008), a general hospital that fails to comply with the applicable statutes or any rules or regulations adopted pursuant thereto, shall be subject to a penalty as determined by the Commissioner pursuant to N.J.S.A. §§ 26:2H-13; 26:2H-16 (2008). Such penalties include fines and loss of licensure.

C. FACILITY LICENSURE AND REGULATORY ISSUES - COMPLIMENTARY SERVICES PROVIDED BY HEALTH CARE FACILITIES

In addition to providing direct medical care services, health care facilities provide numerous complimentary services that require independent licensure and have their own unique governing laws. For instance, health care facilities have licensed pharmacies that are subject to pharmacy regulations. Some health care facilities operate daycare centers or assisted living facilities, each of which are regulated services in most states. As part of their preparedness efforts, health care facilities should examine and evaluate the regulations governing these other services to determine whether regulatory relief is necessary, but assume for planning purposes that such relief will not be forthcoming.

In your plan, consider the following:

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|---|-----------|-------------|-------------|----------------------|-------------------|
| 1 | Identify all services that the health care facility system provides other than inpatient and outpatient hospital services. Consider daycare, cafeteria, pharmacy, lab, home health, hospice, skilled nursing facilities, nursing homes, adult day care and durable medical equipment. | | | | | |
| 2 | Identify which of these services requires a separate license, permit, certification or other governmental approval. | | | | | |

C. FACILITY LICENSURE AND REGULATORY ISSUES - COMPLIMENTARY SERVICES PROVIDED BY HEALTH CARE FACILITIES CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|--|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 3 | Evaluate how a pandemic may impact the ability to comply with statutes and regulations related to these other services. | | | | | |
| 4 | Understand how a pandemic will impact the health care facility's ability to continue providing these other services. Consider, for example, that daycares will most likely be closed early during a pandemic according to the CDC's February 2007 <i>Interim Pre-Pandemic Planning Guidance: Community Strategy for Pandemic Influenza Mitigation in the United States – Early, Targeted, Layered Use of Nonpharmaceutical Interventions</i> . See Appendix A. | | | | | |
| 5 | Evaluate if it is possible to outsource or bring in additional staff or vendors to continue these services during a pandemic, and how such actions could impact the licenses, permits and certifications for the service. | | | | | |

C. FACILITY LICENSURE AND REGULATORY ISSUES - COMPLIMENTARY SERVICES PROVIDED BY HEALTH CARE FACILITIES CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|---|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 6 | Evaluate how non-compliance during a pandemic with statutes and regulations for these other services may impact the health care facility's license and vice versa. | | | | | |
| 7 | Evaluate the ability to discontinue some of these services to reallocate staffing. | | | | | |
| 8 | Determine whether any of these statutes or regulations can be suspended or modified during a pandemic. Begin discussions with the relevant state authorities regarding such suspensions. See Emergency Health Powers Act and Emergency Services Act, Section A of the Legal module. | | | | | |
| 9 | Evaluate liability if the health care facility system is asked to modify some of these services as part of a community surge plan. | | | | | |

C. FACILITY LICENSURE AND REGULATORY ISSUES - SURGE CONSIDERATIONS - LICENSURE

Surge planning is an important component of a health care facility's overall pandemic preparedness activities and is mandated by the federal Department of Health and Human Services for all health care facilities that receive Hospital Preparedness Program funds. Because surge planning involves the introduction of additional beds into a health care facility, or the establishment of new health care facilities to care for patients, current facilities should consider licensing and other regulatory issues associated with surge. See Alternate Care Sites, Section G of the Legal module.

In your plan, consider the following:

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|---|-----------|-------------|-------------|----------------------|-------------------|
| 1 | Determine if the health care facility has, or is required to have, a written surge capacity plan. | | | | | |
| 2 | Identify the agency responsible for oversight of the health care facility's surge plan. | | | | | |
| 3 | Determine if and when the licensing agency should be notified if the health care facility increases its number of beds through implementation of the health care facility's surge plan. | | | | | |
| 4 | Consider whether notification should be given before or after the beds are put into service and whether the duration of service is relevant. | | | | | |

C. FACILITY LICENSURE AND REGULATORY ISSUES - SURGE CONSIDERATIONS
LICENSURE CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|---|-----------|-------------|-------------|----------------------|-------------------|
| 5 | If notification is necessary, create a notification plan that may include a template notification. | | | | | |
| 6 | If the health care facility notified the licensing agency when it implemented its surge beds, consider implementing a mechanism to notify the same agency of the decommissioning of surge beds. | | | | | |
| 7 | Determine whether "surge beds" have to be licensed by the state and, if they do, understand the process for such licensure. | | | | | |
| 8 | Identify the reimbursement mechanisms for these surge beds and consider the impact on reimbursement if the beds are not licensed by the state. See Contract Issues, Third-Party Reimbursement and Alternate Care Sites, Sections G and H of the Legal module. | | | | | |

**C. FACILITY LICENSURE AND REGULATORY ISSUES - SURGE CONSIDERATIONS –
LICENSURE CONTINUED**

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|---|------------------|------------------------|------------------------|---------------------------------|------------------------------|
| 9 | Identify any legal requirements regarding obtaining a Certificate of Need to create surge capacity. See Certificate of Need, Section C of the Legal module. | | | | | |

LICENSURE AND REGULATORY ISSUES - SURGE CONSIDERATIONS - LICENSURE

NEW JERSEY EXAMPLES

2. There is no New Jersey statute or regulation that is directly on point. According to the November 9, 2004 *Influenza Surge Capacity Guidance for General Hospitals* issued by the New Jersey Department of Health and Senior Services (NJDHSS), Office of the State Epidemiologist (“the guidance”), when a health care facility activates its disaster plan (which presumably it will do if it has to institute surge strategies), it must notify NJDHSS at 1-800-792-9770. Interestingly, the guidance specifically contemplates that once a health care facility’s disaster plan is activated, care will be provided in unlicensed areas outside the health care facility and unconventional settings within the health care facility, but does not directly address the issue of adding surge beds. This guidance is included as Appendix B.

C. LICENSURE AND REGULATORY ISSUES - SURGE CONSIDERATIONS - CERTIFICATE OF NEED REQUIREMENTS

Certificate of Need (CN) programs regulate a health care provider’s ability to introduce new or expand existing services by requiring approval from the state before such actions are taken. To the extent that a health care facility is planning to expand bed capacity or other services as part of its surge plan, it may require a CN that could impact the effectiveness of the facility’s surge strategy.

In your plan, consider the following:

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|---|-----------|-------------|-------------|----------------------|-------------------|
| 1 | Determine whether the state has a Certificate of Need (CN) program and identify the applicable statutes and regulations. | | | | | |
| 2 | Identify any CN requirements that could inhibit a health care facility’s ability to continue or discontinue services during a pandemic. | | | | | |
| 3 | Identify any CN requirements related to reduction in the number of staffed beds. | | | | | |

C. LICENSURE AND REGULATORY ISSUES - SURGE CONSIDERATIONS - CERTIFICATE OF NEED REQUIREMENTS CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|--|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 4 | Identify any CN requirements for increasing the number of beds. To the extent that such requirements exist, determine whether they are applicable to surge beds. If they are applicable to surge beds, determine whether the requirements can be suspended during a pandemic since typical CN processes do not yield rapid determinations. | | | | | |
| 5 | Identify any services that the health care facility may want to begin providing during a pandemic for which a CN is required. | | | | | |
| 6 | Identify any services that the health care facility may want to expand during a pandemic for which a CN is required. | | | | | |
| 7 | Understand the mechanisms for expedited review if the health care facility may need a CN to discontinue or implement services during a pandemic. | | | | | |

FACILITY LICENSURE AND REGULATORY ISSUES - SURGE CONSIDERATIONS - CERTIFICATE OF NEED REQUIREMENTS

NEW JERSEY EXAMPLES

1. New Jersey has a Certificate of Need (CN) program. The relevant statutes are N.J.S.A. § 26:2H-1 et seq. (2008) and the relevant regulations can be found in the New Jersey Administrative Code Title 8, Chapter 33.

2. Voluntary closure of a general hospital requires a CN (N.J.A.C. § 8:33-3.2(b) (2008)). While there is an expedited review process for CNs, closures are not eligible for this process.

Pursuant to N.J.A.C. § 8:33-3.2(c) (2008), discontinuance of a hospital service or satellite emergency department does not require a CN as long as the discontinuance does not result in problems of access to populations historically served by the service, and as long as the service is not one which is required to be a component of an inpatient health care facility. At least 60 days prior to discontinuing a service, the provider must notify the Office of Certificate of Need and Health Care Facility Licensure ("Office of CN"), providing an explanation of why the discontinuance will not result in access problems. After reviewing the notification and explanation, the Office of CN will determine whether the discontinuance requires a CN and notify the provider of its decision. If a CN is required, it will be eligible for expedited review. To the extent that a provider will be forced to discontinue certain services during a pandemic, it may be difficult to comply with the 60-day notice requirement. Providers should consider discussing this difficulty with the Office of CN now and planning for how to comply with the regulations. Providers must also remember that if they discontinue any service that requires a CN for more than two years, they will need a CN to re-establish the service (N.J.A.C. § 8:33-3.2(a) (2008)).

3. In New Jersey, a reduction in the number of licensed beds by licensure and/or health planning category does not require a CN (N.J.A.C. § 8:33-3.4(a)(2) (2008)).

4. Generally, an increase in the number of licensed beds by licensure and/or health planning category requires a CN and may be eligible for expedited review (N.J.A.C. §§ 8:33-3.4(a)1; 8:33-5.1 (2008)). In a hospital, however, additions of medical/surgical, adult intensive care, adult critical care, basic obstetric and pediatric beds are exempt from CN requirements (N.J.S.A. § 26:2H-7 et seq. (2008)). As a result, implementation of surge beds should not require a CN.

A nursing home or long-term care facility must obtain a CN to increase its total number of licensed beds by more than ten beds or ten percent of its licensed capacity, whichever is less, within a five-year period (N.J.S.A. § 26:2H-7.2 (2008); N.J.A.C. § 8:33-6.1(a)(34) (2008)). Such facilities should discuss with the Office of CN the applicability of these requirements to surge beds.

5-6. During a pandemic, a health care facility may want to begin providing services in an alternate care site. Pursuant to N.J.A.C. § 8:33-3.5 (2008), a CN is needed for the establishment of a medical care facility. If the alternate care site qualifies as a “medical care facility” as that term is defined in N.J.A.C. § 8:33-1.3 (2008) and is not otherwise excluded from review under N.J.S.A. § 26:2H-7 et seq. (2008), a hospital will need a CN prior to operating the alternate care site.

7. In New Jersey, during an emergency situation that demands rapid action, all CN applications are entitled to expedited review (N.J.A.C. § 8:33-5.1(b)(1) (2008)). A new expedited review cycle begins each month, and the commissioner must make a decision on each application within 90 days (N.J.A.C. § 8:33-5.2(a) (2008)). While this is faster than the normal CN review process, it is still rather long for decisions that need to be made in the midst of a pandemic. Providers should consult with the Office of CN regarding an alternative to the expedited review process during a pandemic.

C. FACILITY LICENSURE AND REGULATORY ISSUES - MEDICARE CONDITIONS OF PARTICIPATION

The Centers for Medicare and Medicaid Services (CMS) requires health care facilities to meet certain conditions to participate in federal health care programs such as Medicare and Medicaid. Some of these conditions of participation (CoP) will be difficult to meet during an emergency or disaster. Under Section 1135 of the Social Security Act, the Secretary of Health and Human Services may waive compliance with some of these CoPs, but it is difficult to predict whether such a waiver will be forthcoming, or the scope of the waiver if one is issued. As a result, health care facilities should begin to identify any such CoPs now and must consider the legal and regulatory impact on their facility for failure to comply with CoPs. This section addresses the legal issues related to hospital CoPs.

In your plan, consider the following:

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|--|-----------|-------------|-------------|----------------------|-------------------|
| 1 | Identify the basic conditions of participation (CoP) for a health care facility and the services it provides. See 42 C.F.R. § 482 et seq. (2008) for the CoPs for hospitals. | | | | | |
| 2 | Assess which CoPs are most likely to pose a compliance challenge during a pandemic. | | | | | |
| 3 | Identify any penalties to the health care facility for failing to comply with CoPs during a pandemic. | | | | | |

C. LICENSURE AND REGULATORY ISSUES - MEDICARE CONDITIONS OF PARTICIPATION CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|---|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 4 | Determine whether submission of a claim during a pandemic requires a certification that the health care facility is in compliance with all CoPs. | | | | | |
| 5 | Evaluate the potential liability that could result from a certification of compliance during an emergency when the health care facility is not, in fact, in compliance with all CoPs. | | | | | |
| 6 | Develop a process for obtaining and evaluating the impact of any Section 1135 waiver that is issued by the Secretary of Health and Human Services. | | | | | |

C. FACILITY LICENSURE AND REGULATORY ISSUES - TREATMENT AND DISPOSITION OF THE DEAD

Experts are predicting that if the next pandemic is as severe as the influenza pandemic of 1918, it could result in the death of approximately 1.9 million people, many of whom will die in a health care facility. Health care facilities need to be prepared to handle the increased volume of deaths in compliance with all applicable laws.

In your plan, consider the following:

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|--|-----------|-------------|-------------|----------------------|-------------------|
| Jurisdiction of the State Medical Examiner | | | | | | |
| 1 | Determine whether deaths in the health care facility related to pandemic influenza will be under the jurisdiction of the state medical examiner (SME). | | | | | |
| 2 | To the extent that such deaths will be under the jurisdiction of the SME, understand the process for reporting the deaths. | | | | | |
| 3 | Initiate discussions with the SME regarding handling large volumes of deaths in a manner that complies with the law but does not compromise health care facility operations. | | | | | |

C. FACILITY LICENSURE AND REGULATORY ISSUES - TREATMENT AND DISPOSITION OF THE DEAD CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|--|--|-----------|-------------|-------------|----------------------|-------------------|
| APPLICABLE STATUTES AND REGULATIONS | | | | | | |
| 4 | Identify the statutes and regulations that govern death of persons in the health care facility. Consider that in the early stages of a pandemic, it may be unclear if the deaths are from natural causes, the first wave of a pandemic or bioterrorist attack. | | | | | |
| 5 | Determine who within the health care facility has the authority to pronounce a death. | | | | | |
| 6 | Determine how and when a death certificate is executed. | | | | | |
| 7 | Identify requirements related to notification of family members. | | | | | |
| 8 | Identify the requirements regarding disposition and handling of the deceased in a health care facility. Note any statutes or regulations that require compliance with the burial customs of specific religions. | | | | | |

C. FACILITY LICENSURE AND REGULATORY ISSUES - TREATMENT AND DISPOSITION OF THE DEAD CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|----|---|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 9 | Identify any statutes or regulations that relate to disposition and handling of remains during a pandemic. | | | | | |
| 10 | Evaluate how a pandemic will impact a health care facility's ability to comply with the relevant statutes and regulations. | | | | | |
| 11 | Identify any statutes or regulations that should be modified or suspended during a pandemic because they will impair a health care facility's ability to respond to the pandemic effectively and efficiently. | | | | | |
| 12 | Determine whether the statutes and regulations governing other parties who handle the deceased (e.g., SME, funeral directors) will impact the health care facility's ability to handle the deceased. | | | | | |

C. FACILITY LICENSURE AND REGULATORY ISSUES - TREATMENT AND DISPOSITION OF THE DEAD CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|------------------|--|-----------|-------------|-------------|----------------------|-------------------|
| LIABILITY | | | | | | |
| 13 | Determine the potential for liability exposure for failure to comply with applicable statutes and regulations. | | | | | |
| 14 | Evaluate the potential liability to third parties that can arise in connection with the handling of remains. Consider claims for negligent or intentional infliction of emotional distress, claims based on property rights, negligent mishandling of a corpse and violation of requirements to respect religious customs. | | | | | |
| PLANNING | | | | | | |
| 15 | Develop a plan for handling the deceased within the confines of the law. | | | | | |
| 16 | Build relationships with others in the community who handle the deceased and create a community plan regarding the deceased in a pandemic. | | | | | |

C. FACILITY LICENSURE AND REGULATORY ISSUES - TREATMENT AND DISPOSITION OF THE DEAD CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|----|--|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 17 | Consider the community's ability to establish an alternate morgue site and the health care facility's ability to transport the dead to the site. | | | | | |
| 18 | Develop a plan for responding to a family's request for release of a relative's body during a pandemic. | | | | | |

FACILITY LICENSURE AND REGULATORY ISSUES - TREATMENT AND DISPOSITION OF THE DEAD

NEW JERSEY EXAMPLES

Jurisdiction of State Medical Examiner

1. Pursuant to N.J.S.A. § 52:17B-86 (2008), a medical examiner shall conduct an investigation when, among other things, a death occurs within 24 hours of admission to a hospital or results from a cause that might constitute a threat to public health. When thinking about pandemic influenza, these two causes of death will bring all pandemic influenza deaths in the health care facility under the jurisdiction of the medical examiner's office.
2. Upon a death caused by either of the reasons listed in Item 1, the physician in attendance or any other person present has the duty to immediately notify the county medical examiner and the county prosecutor of the facts concerning the time, place, manner and circumstances of the death. Immediately upon notification, the county medical examiner or his/her assistant will take charge of the body (N.J.S.A. § 52:17B-87 (2008)).

Applicable Statutes and Regulations

5. A physician is permitted to determine and pronounce death in all cases. A licensed registered professional nurse may determine and pronounce death in all cases, except those of brain death (N.J.S.A. §§ 26:6A-4; 26:6-8.1 (2008)).
6. Pursuant to N.J.S.A. § 26:6-8 (2008), "within a reasonable time, not to exceed 24 hours after the pronouncement of death, the attending, covering or resident physician or the county medical examiner shall execute the death certification."
7. N.J.S.A. § 26:2H-5e (2008) provides "a general or special hospital, nursing home or assisted living residence licensed pursuant to P.L. 1971, c. 136 (N.J.S.A. § 26:2H-1 et seq. (2008)) shall...adopt and maintain written policies and procedures to delineate the responsibilities of its staff for prompt notification of a family member, guardian or other designated person about a patient's death and confirmation and written documentation of that notification."

8. The statutes governing the disposal of dead bodies generally appear in N.J.S.A. § 26:6-1 et seq. (2008) and N.J.A.C. § 8:9.1-1 et seq. (2008). The former of these provisions mainly discusses procedural issues that arise in disposing of the deceased. The latter provides more detailed guidance to individuals and others handling human remains by laying out both the time frame and the lawful manner in which to dispose of the deceased.

If the person died from or had a contagious condition, the hospital will have to place with the remains a written notification of the deceased's contagious condition and provide written notification of the same to the funeral director who is responsible for the handling and disposition of the body (N.J.S.A. § 26:6-8.2 (2008)).

9. During or in response to a public health emergency, N.J.S.A. § 26:13-7 (2008) controls the handling and disposing of human remains. This section specifies that, in the context of a public health emergency, the commissioner of NJDHSS, State Medical Examiner, and Commissioner of Environmental Protection may take reasonable and necessary measures to provide for the safe disposition of deceased persons. These measures may include, but are not limited to, temporary mass burial or other interment, cremation, disinterment, transportation and disposition of human remains. The statute further specifies that, to the extent possible when implementing these measures, the authorities should consider the religious, cultural, family and individual beliefs of the deceased person.

Additionally, the commissioner of NJDHSS, State Medical Examiner, and Commissioner of Environmental Protection may require that the persons in charge of the disposition of any human remains maintain a written electronic record of each deceased person. To the extent that a health care facility would be in charge of disposition of remains, it should be prepared to implement or maintain the required system during an emergency.

Finally, while N.J.A.C. § 8:9-1.1 (2008) controls the manner and timeframe in which to dispose of the deceased, it contains an exception excusing hospitals from complying with its requirements when the governor has declared a public health emergency and prescribed other conditions for the disposition of remains.

10. One foreseeable difficulty in complying with the Emergency Health Powers Act stems from the requirement that the health care facility maintain "written electronic records" of each deceased person, identifying the decedent and the circumstances of death and disposition (N.J.S.A. § 26:13-7 (2008)). Where a pandemic is killing large numbers of people and a health care facility is experiencing staffing shortages, the sheer logistics of maintaining a written record of each deceased person is certainly daunting. A health care facility implementing a preparedness plan for a public health emergency may want to consider methods of streamlining and organizing a system, so that staff can gather this information about the deceased quickly and efficiently.

12. If all pandemic influenza deaths come under the jurisdiction of and must be investigated by a county medical examiner, the county and State Medical Examiner's offices may become quickly overwhelmed. The sheer volume of cases may impede the offices' ability to take control of bodies in a timely manner, thus leaving health care facilities in the position of having to store these bodies for longer amounts of time than they are accustomed to.

Liability

13. Failure to report a death caused by the reasons set forth in N.J.S.A. § 52:17B-86 (2008) (see Item 1) is a misdemeanor (N.J.S.A. § 52:17B-90 (2008)). Persons who fail to comply with the applicable statutes and regulations for the disposal of remains under N.J.S.A. § 26:6-8.4 (2008) can be subject to a fine of up to \$1,000.00 for each violation of the act. So long as the person acts in good faith, however, he/she will not be subject to such penalty. For failure to comply with orders issued under the Emergency Health Powers Act (N.J.S.A. § 26:13-7 (2008)), see Emergency Health Powers Act, Section A of the Legal module.

14. New Jersey "has recognized a quasi property right in the body of a dead person. '[I]t is now the prevailing rule that the right to bury the dead and preserve the remains is a quasi right in property, the infringement of which may be redressed by an action in damages'" (*Strachan v. John F. Kennedy Memorial Hospital*, 109 N.J. 523, 531 (N.J. 1988) quoting *Spiegel v. Evergreen Cemetery Co.*, 117 N.J.L. 90, 93 (Sup.Ct.1936)).

According to the New Jersey Appellate Court, "conceivably a claim for relief for emotional distress or physical disability, or both, [related to the misplacement of a corpse] might be based on (1) plaintiffs' property or other right with respect to the corpse of their deceased child; or (2) an implied contract with the hospital which may have been violated; or (3) conduct by the hospital that would warrant recovery for the tort of outrage; or (4) a deviation from the standard of care reasonably to be expected of a hospital in dealing with corpses and the reasonable foreseeability that such a deviation would cause emotional and substantial physical disability with respect to persons normally constituted" (*Muniz v. United*

Hospitals Medical Center Presbyterian Hospital, 153 N.J. Super. 79, 82 (App.Div. 1977)).

See also *Lacy v. Cooper Hospital/University Medical Center*, 745 F. Supp. 1029 (D.N.J. 1990) for a discussion of infliction of emotional distress with respect to mishandling a corpse.

C. FACILITY LICENSURE AND REGULATORY ISSUES - OUTDATED MEDICATIONS

As part of pandemic preparedness plans, many health care facilities are considering the use of outdated medications once they have exhausted their supply of current medications. Before health care facilities undertake such actions, it is important that they understand the legal requirements surrounding use of outdated medications and the liability that could stem from such actions.

In your plan, consider the following:

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|--------------------|---|-----------|-------------|-------------|----------------------|-------------------|
| FEDERAL LAW | | | | | | |
| 1 | Identify any federal statutes or regulations that govern the use of expired medications within the health care facility or by a pharmacy, 42 CFR § 482.25(b)(3) (2008). | | | | | |
| 2 | Determine whether, and how probable it is that, the relevant federal regulations can be waived during a pandemic. | | | | | |
| STATE LAW | | | | | | |
| 3 | Identify any state statutes or regulations that govern the use of expired medications within the health care facility or by a pharmacy. | | | | | |

C. FACILITY LICENSURE AND REGULATORY ISSUES - OUTDATED MEDICATIONS CONTINUED

| | | | | | | |
|------------------|---|--|--|--|--|--|
| 4 | Determine whether, and how probable it is that, the relevant state regulations can be waived during a pandemic. See Emergency Health Powers Act and Emergency Services Laws, Section A of the Legal module. | | | | | |
| LIABILITY | | | | | | |
| 5 | Understand the penalties for using outdated medications under both state and federal laws. | | | | | |
| 6 | Consider the legal theories under which a health care facility may be held liable for harms to third parties associated with the use of outdated medications (assuming no legal prohibitions on such use). | | | | | |

FACILITY LICENSURE AND REGULATORY ISSUES - OUTDATED MEDICATIONS

NEW JERSEY EXAMPLES

Federal Law

1. The Medicare conditions of participation for a hospital state: "outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use" (42 CFR § 482.25(b)(3) (2008)).
2. Health care facilities may want to enter into discussions with the U.S. Department of Health and Human Services and Centers for Medicare and Medicaid Services to discuss the likelihood of obtaining a Section 1135 waiver for the segment of the condition of participation that prevents a hospital from using outdated pharmaceuticals (42 CFR § 482.25(b)(3) (2008)). Health care facilities should not assume that such a waiver will be forthcoming, and should create their emergency plans based on the assumption that this prohibition will remain in full force and effect.

State Law

3. Within the hospital licensing regulations, N.J.A.C. § 8:43G-23.6 (2008) requires that a hospital dispose of any outdated medications. Within the pharmacy regulations, N.J.A.C. § 13:39-7.18 (2008) prohibits a pharmacy from dispensing or maintaining in active stock for use or sale any outdated drugs. The Board of Pharmacy also has the ability to label any drug that is suspected of being outdated, pursuant to N.J.S.A. § 45:14-48 (2008).
4. During an emergency in New Jersey, the governor could suspend the state regulations discussed in Item 3. Such a suspension would be of little help if the federal prohibition on the use of outdated pharmaceuticals remains in effect.

Liability

5. Use of outdated medications violates a Medicare condition of participation that, in turn, jeopardizes the hospital's Medicare eligibility. It also violates New Jersey statutes and regulations, the penalty for which varies based on severity of the violation (N.J.A.C. §§ 8:43E-3.1, 3.4 (2008) and N.J.S.A. § 26:2H-13 (2008)).

C. FACILITY LICENSURE AND REGULATORY ISSUES - HOME MEDICATIONS

In addition to using outdated medications, many health care facilities are considering asking patients to bring previously acquired medications with them for use during their inpatient stay ("home medications"). Health care facilities should be conversant with the laws governing use of home medications, and ensure that any plans to use these medications during a pandemic are compliant.

In your plan, consider the following:

| ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|--------------------|---|-------------|-------------|----------------------|-------------------|
| FEDERAL LAW | | | | | |
| 1 | Identify any federal statutes or regulations that govern the use of medications within the health care facility that a patient has previously acquired and brought with him/her ("home medications"). | | | | |
| 2 | Identify any federal statutes or regulations that govern a patient's ability to self-administer medications while in a health care facility. | | | | |
| STATE LAW | | | | | |
| 3 | Identify any state statutes or regulations that govern the use of home medications within the health care facility. | | | | |

C. FACILITY LICENSURE AND REGULATORY ISSUES - HOME MEDICATIONS CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|--------------------------------|--|-----------|-------------|-------------|----------------------|-------------------|
| 4 | Identify any state statutes or regulations that govern a patient's ability to self-administer medications while in a health care facility. | | | | | |
| POLICIES AND PROCEDURES | | | | | | |
| 5 | Review the health care facility's current policies regarding the use of home medications. | | | | | |
| 6 | Draft policies governing the use of home medications during a pandemic. | | | | | |
| 7 | Review the health care facility's current policies regarding a patient's ability to self-administer medications while in the facility. | | | | | |
| 8 | Draft policies governing the self-administration of medications during a pandemic. | | | | | |
| LIABILITY | | | | | | |
| 9 | Consider the legal theories under which a health care facility may be held liable for harms to third parties associated with the use of home medications and self-administration of medications. | | | | | |

FACILITY LICENSURE AND REGULATORY ISSUES - HOME MEDICATIONS

NEW JERSEY EXAMPLES

State Law

3. As part of the licensure regulations, New Jersey allows each hospital's pharmacy committee to set a policy for use of home medicines. Under N.J.A.C. § 8:43G-23.2(a)(3) (2008), "[t]he pharmacy and therapeutics committee, or its equivalent, shall review, approve and ensure implementation of policies and procedures addressing at least the following areas...[u]se of patients' previously acquired drugs, including requirement for physician orders and pharmacy identification of the drugs before use."

4. Under N.J.A.C. § 8:43G-23.2(a)(13) (2008), each pharmacy and therapeutics committee "shall review, approve, and ensure implementation of policies and procedures addressing...self-administration of drugs, if permitted by the hospital, including a requirement for written prescriber orders, storage of drugs, labeling of drugs, documentation of self-administration in the patient medical record, patient training and education, and precautions to ensure that a patient does not take the drugs to another patient."

C. FACILITY LICENSURE AND REGULATORY ISSUES - PANDEMIC SPENDING GUIDELINES AND COMPLIANCE

There are multiple sources of federal funding for health care facility pandemic preparedness activities including the Department of Health and Human Services (DHHS) Hospital Preparedness Program and the CDC Public Health Preparedness Cooperative Agreements. Some of these funds may come directly to the health care facility, while other funds may come through an intermediary such as the state health department; hospital association; or state or local government. As with all federal funding, there are conditions associated with receipt of this funding and the recipient must demonstrate that it has complied with these conditions. The Department of Health and Human Services Office of the Inspector General (OIG) Fiscal Year 2007 Work Plan indicates that the OIG will be focusing attention on the expenditure of pandemic influenza preparedness grant funds by recipients. Health care facilities, as a result, must ensure that their expenditure of funds is appropriate and documented.

In your plan, consider the following:

| ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|--|-----------|-------------|-------------|----------------------|-------------------|
| 1 Determine if the health care facility is receiving federal funds for pandemic influenza preparedness activities including funds from the DHHS Hospital Preparedness Program or CDC Public Health Preparedness Cooperative Agreements. | | | | | |
| 2 If the health care facility is receiving federal pandemic influenza planning funds, determine if the health care facility is in compliance with the terms of the funding. | | | | | |
| 3 Maintain documentation showing that the health care facility used the funds appropriately and in compliance with all applicable terms. | | | | | |

C. FACILITY LICENSURE AND REGULATORY ISSUES - ZONING AND LAND USE ISSUES

Zoning ordinances are enacted in municipalities across the country to regulate land use and protect the rights of property owners. Typically, zoning ordinances divide land into categories according to use: business, residential, mixed use or industrial. By categorizing uses, zoning ordinances seek to locate them in the most appropriate areas. Zoning ordinances can also specify details about structures in that area including setback lines; parking restrictions; the height and bulk of buildings; and the size and location of open spaces. These ordinances may impact a health care facility's ability to implement its pandemic influenza plan to the extent that such plans call for the erection of new buildings or the relocation of services to other areas of the municipality.

In your plan, consider the following:

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|----|---|-----------|-------------|-------------|----------------------|-------------------|
| 1 | Identify any zoning or land use regulations that could impede the health care facility's implementation of its pandemic influenza plan. | | | | | |
| 1a | Consider any zoning or land use regulations that could prevent the use of new structures (e.g., tents or trailers) to expand capacity. | | | | | |
| 1b | Consider any zoning or land use regulations that could prevent the health care facility from implementing desired security measures such as fences or blast-proof window coverings. | | | | | |

C. FACILITY LICENSURE AND REGULATORY ISSUES - ZONING AND LAND USE ISSUES
CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|---|-----------|-------------|-------------|----------------------|-------------------|
| 2 | Determine whether proposed sites for an alternate care site are properly zoned. | | | | | |
| 3 | Evaluate options for seeking a zoning variance or other exemption for any identified regulations prior to a pandemic. | | | | | |
| 4 | Determine whether such regulations may be waived during a pandemic. See Emergency Health Powers Act and Emergency Services Laws, Section A of the Legal module. | | | | | |

FACILITY LICENSURE AND REGULATORY ISSUES -ZONING AND LAND USE ISSUES

NEW JERSEY EXAMPLES

- 1a.** Some zoning ordinances may prevent a health care facility from erecting tents or trailers outside of the health care facility to accommodate increased patient volumes during a pandemic.
- 1b.** Some ordinances may require setbacks that will impede a health care facility's ability to install security fences.

D. HIPAA - INITIAL PLANNING

During an emergency, including a pandemic, health care facilities should assume that the Health Insurance Portability and Accountability Act of 1996 (HIPAA) will remain in full force and effect; therefore, all uses or disclosures of protected health information (PHI) must be HIPAA compliant. Information will have to be shared quickly during an emergency. As a result, health care facility counsel should be familiar with the HIPAA exceptions that apply during an emergency and those that do not. Appendix C, *Sharing Information During Disasters: HIPAA Implications*, is an important resource that readers can use to help gain this familiarity and address the assignments included below. Health care facilities must also be familiar with their state’s privacy laws and understand their interaction with HIPAA.

In your plan, consider the following:

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|---|-----------|-------------|-------------|----------------------|-------------------|
| 1 | Identify the state privacy laws regarding medical information, N.J.S.A. § 26:2H-12.8 (2008) and N.J.A.C. § 13:35-6.5 (2008). | | | | | |
| 2 | Determine whether the state privacy law pre-empts HIPAA in the applicable areas discussed in this section because the state law is more protective. | | | | | |

D. HIPAA - INITIAL PLANNING CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|---|-----------|-------------|-------------|----------------------|-------------------|
| 3 | Identify those uses and disclosures of protected health information (PHI) that will be necessary during a pandemic outside of treatment, payment and health care operations. Consider uses and disclosures related to public health activities, notification of family members, responses to general inquiries about a patient's status and sharing of information for response coordination. | | | | | |
| 4 | Identify all HIPAA exceptions that may apply to the use or disclosure of PHI during a pandemic. (See Appendix C and H) | | | | | |
| 5 | Be familiar with the Office of Civil Rights' HIPAA emergency planning tool available at: http://www.hhs.gov/ocr/hipaa/decisiontool . | | | | | |
| 6 | Examine the health care facility's existing HIPAA policies to determine whether they allow the health care facility to share information pursuant to the applicable HIPAA exceptions. | | | | | |

D. HIPAA - INITIAL PLANNING CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|---|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 7 | Amend policies and procedures to the extent necessary to account for the use of the applicable HIPAA exceptions during a pandemic. | | | | | |
| 8 | Amend policies and procedures with respect to the creation of HIPAA accounting disclosure logs to take into consideration the fact that a public health authority may request ongoing access to medical records of all patients treated for pandemic influenza. | | | | | |
| 9 | Review (and amend, where appropriate) existing business associate agreements to account for disclosures that may be necessitated by a pandemic. | | | | | |

D. HIPAA - SPECIFIC EXCEPTIONS AND APPLICATIONS

There are various exceptions to HIPAA that may apply during a pandemic to enable health care facilities to share protected health information more easily. Health care facilities should incorporate the application of these exceptions into their planning process.

In your plan, consider the following:

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|--|-----------|-------------|-------------|----------------------|-------------------|
| TREATMENT, PAYMENT, HEALTH CARE OPERATIONS | | | | | | |
| 1 | Be familiar with the scope of "treatment" and how it may expand the types of allowable uses and disclosures in a pandemic. Consider that treatment includes not only sharing information with other providers, but also sharing with others who help coordinate patient care (e.g., emergency relief workers). | | | | | |
| REQUIRED BY LAW | | | | | | |
| 2 | Understand the application of the "required by law" HIPAA exception, 45 CFR § 164.512(a) (2008). | | | | | |
| 3 | Identify the state laws regarding reporting of communicable diseases. | | | | | |
| 4 | Determine whether influenza is a reportable disease under the state law identified in Item 3. | | | | | |

D. HIPAA - SPECIFIC EXCEPTIONS AND APPLICATIONS CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---------------------------------|---|-----------|-------------|-------------|----------------------|-------------------|
| 5 | Develop HIPAA compliant policies, procedures and mechanisms for complying with the mandatory state reporting laws identified in Item 3. | | | | | |
| PUBLIC HEALTH ACTIVITIES | | | | | | |
| 6 | Understand the application of the “public health activities” HIPAA exception, 45 CFR § 164.512(b) (2008). | | | | | |
| 7 | Determine which entities within the state are “public health authorities,” as that term is defined in 45 CFR § 164 (2008). Consider hospital coordinating centers, emergency operations centers and medical control officers. | | | | | |
| 8 | Understand the health care facility’s ability under HIPAA to inform an individual or others, such as family members or employers, that the individual may have been exposed to a communicable disease, 45 CFR § 164.512(b)(1)(iv) (2008). | | | | | |

D. HIPAA - SPECIFIC EXCEPTIONS AND APPLICATIONS CONTINUED

| ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|--|-----------|-------------|-------------|----------------------|-------------------|
| 9 Determine if and how the health care facility will conduct HIPAA compliant notifications of exposure during a pandemic. | | | | | |
| AVERTING A THREAT TO HEALTH OR SAFETY | | | | | |
| 10 Understand the application of the "averting a threat to health or safety" HIPAA exception, 45 CFR § 164.512(j) (2008). | | | | | |
| NATIONAL SECURITY | | | | | |
| 11 Understand the application of the "national security" HIPAA exception, 45 CFR § 164.512(k)(2) (2008). | | | | | |
| FACILITY DIRECTORY | | | | | |
| 12 Understand the application of the "facility directory" HIPAA exception, 45 CFR § 164.510(a) (2008). | | | | | |
| 13 Determine whether existing health care facility policies regarding operation of the facility directory will be sufficient during a pandemic, or whether they should be amended to account for the expected increased call volume. | | | | | |

D. HIPAA - SPECIFIC EXCEPTIONS AND APPLICATIONS CONTINUED

| ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|----------------------------|--|-------------|-------------|----------------------|-------------------|
| NOTIFICATION | | | | | |
| 14 | Understand the application of the "notification" HIPAA exception, 45 CFR § 164.510(b) (2008). | | | | |
| 15 | Determine whether the health care facility is going to partner with any disaster relief organization to help identify, locate and notify disaster victims' family members. | | | | |
| SECTION 1135 WAIVER | | | | | |
| 16 | Understand the process for obtaining, and the impact of, a Section 1135 waiver by the Secretary of Health and Human Services with respect to the application of HIPAA during a pandemic. See Appendix C. | | | | |
| 17 | Determine how the health care facility will obtain a copy of a Section 1135 waiver if one is issued. | | | | |
| 18 | Determine who will carefully review the Section 1135 waiver to understand its implications. | | | | |
| 19 | Develop processes for implementing any changes allowed by a Section 1135 waiver. | | | | |

HIPAA - SPECIFIC EXCEPTIONS AND APPLICATIONS

NEW JERSEY EXAMPLES

Required by Law

3. N.J.S.A. § 26:4-19 (2008) requires:

Every physician, superintendent or other person having control or supervision over a state, county or municipal hospital, sanatorium or other public or private institution in which any person ill or infected with any disease required by law or the State Sanitary Code to be reported is received for care or treatment shall, within 24 hours after any such patient has been received into the institution, report the fact to the health officer or other officer or employee designated to receive such reports by the local board of health having jurisdiction over the territory in which the institution is located.

The report shall be in writing in the name of the physician, superintendent or other person having charge over the institution and shall set forth the name and age of the ill or infected person and the exact place of his residence or the name of the place from which he was received into the institution, together with the date upon which he was received and such other information as may be required by regulation of the State Department of Health.

N.J.A.C. § 8:57-1 et seq. (2008) contains regulations related to reportable diseases.

4. New Jersey's list of reportable diseases can be found in N.J.A.C. § 8:57-1.3 (2008). While influenza is not specifically listed as a reportable disease, "any outbreak or suspected outbreak" of a disease is included in the list.

E. EMTALA - INITIAL PLANNING

Despite all of the focus on “surge capacity,” there is increasing recognition that health care facilities simply will not have the ability to treat everyone when faced with a rapid influx of patients from a public health emergency, such as a pandemic. Health care facilities will have to choose which patients will be treated and which will not. It is this decision – the decision to turn away patients with minor ailments – that creates significant concern among health care facilities. This is because denying care violates a fundamental tenet of the American health care system, and because it potentially violates the Federal Emergency Medical Treatment and Active Labor Act (EMTALA), which requires health care facilities to screen and stabilize all who present themselves to emergency departments for care. Health care facilities must understand the contours and nuances of their responsibilities under EMTALA during disasters, as well as ways in which they can protect themselves from liability for potential, but unavoidable, violations. Appendix D, *EMTALA Compliance in Disaster Circumstances*, is an important resource that the reader can use to help gain this familiarity and address the assignments included below.

In your plan, consider the following:

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|---|-----------|-------------|-------------|----------------------|-------------------|
| 1 | Be familiar with EMTALA (42 U.S.C. § 1395dd (2008)); the applicable regulations (42 CFR § 489 (2008)); and the Interpretive Guidelines in the State Operations Manual. See also <i>Waiving EMTALA Sanctions in Response to Public Health Emergencies</i> Brooke Courtney. Biosecurity and Bioterrorism. September 1, 2008, 6(3): 213-218. doi:10.1089/bsp.2008.0825. | | | | | |
| 2 | Understand the EMTALA requirements that health care facilities must have qualified medical personnel (QMP) who provide medical screening examinations (MSE) and staff who provide stabilization services within the capabilities of the health care facility. | | | | | |

E. EMTALA - INITIAL PLANNING CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|---|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 3 | Understand the health care facility's existing diversion policies since they may be needed during a pandemic. | | | | | |
| 4 | Identify any local, regional or state protocols that could prevent health care facilities from going on diversion during a pandemic. | | | | | |
| 5 | Modify the health care facility's diversion policies to: (i) ensure that the health care facility will have sufficient documentation of the circumstances that led them to exceed their capabilities; (ii) specify the point at which the health care facility emergency department is operating at capacity; (iii) provide the decision-making authority within the health care facility for such a determination; (iv) outline notification mechanisms required by state or local law; and (v) establish transfer protocols consistent with EMTALA. | | | | | |
| 6 | Understand the limits of a health care facility's ability to delay an MSE. | | | | | |

E. EMTALA - INITIAL PLANNING CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|----|---|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 7 | Develop policies regarding MSEs for persons seeking prescription refills. | | | | | |
| 8 | Consider adopting special disaster QMP designations (for appropriately qualified personnel) in a board approved document. | | | | | |
| 9 | Understand the civil monetary penalties for violating EMTALA. | | | | | |
| 10 | Understand those damages that may be recovered by a plaintiff in a civil action. Identify how the courts that have jurisdiction over the health care facility analyze the statutory provision that dictates if a plaintiff prevails, he/she is only entitled to "obtain those damages available for personal injury under the law of the state in which the health care facility is located." | | | | | |

E. EMTALA - SPECIFIC EXCEPTIONS AND APPLICATIONS

There are various exceptions to EMTALA that may apply during a pandemic to relieve a health care facility of some of its EMTALA obligations. These exceptions are not easy to understand or apply. As a result, a health care facility must examine these exceptions as part of its planning process so that it will not have to waste valuable time in the midst of a pandemic trying to understand what it is required to do under EMTALA.

In your plan, consider the following:

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|-----------------------------|---|-----------|-------------|-------------|----------------------|-------------------|
| EXCEPTIONS TO EMTALA | | | | | | |
| 1 | Understand the exception to EMTALA for inappropriate transfers during a national emergency, 42 CFR § 489.24(a)(2) (2008). | | | | | |
| 2 | Understand how the exception applies to the various EMTALA requirements including provision of a MSE, stabilization services and transfers. | | | | | |
| 3 | Determine whether state or local emergency services plans qualify as a "community response plan" as that term is used in the EMTALA Interpretive Guidelines (TAG A406 Interpretative Guidelines § 489.24(a)). Consider whether the plans designate specific entities with the responsibility of handling certain categories of patients during catastrophic events. | | | | | |

E. EMTALA - SPECIFIC EXCEPTIONS AND APPLICATIONS CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|----------------------------|---|-----------|-------------|-------------|----------------------|-------------------|
| SECTION 1135 WAIVER | | | | | | |
| 4 | Understand the process for obtaining and the impact of a Section 1135 waiver with respect to the application of EMTALA during a pandemic. See Appendix D. | | | | | |
| 5 | Determine how the health care facility will obtain a copy of a Section 1135 waiver if one is issued. | | | | | |
| 6 | Determine who will carefully review the Section 1135 waiver to understand its implications. | | | | | |
| 7 | Develop processes for implementing any changes allowed by a Section 1135 waiver. | | | | | |

E. EMTALA - SPECIFIC EXCEPTIONS AND APPLICATIONS CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|--|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 8 | Pursuant to the Pandemic and All Hazards Preparedness Act (P.L. 109-417), a Section 1135 waiver may be based on compliance with a state pandemic preparedness plan that provides for direction or relocation of individuals to receive a medical screening exam. Determine whether the state plan provides for such direction or relocation. | | | | | |

F. STAFFING ISSUES - INITIAL PLANNING

Addressing staffing issues is critical to any effective pandemic preparedness plan. In fact, an entire module of this series is devoted to human resources planning (see HR module). In addition to considering the operational issues discussed in the HR module, health care facilities must also consider how operational planning will be impacted by the plethora of state and federal employment laws and regulations. This section of the Legal module is dedicated to addressing the legal considerations associated with human resources and staffing issues presented by pandemic preparedness plans.

In your plan, consider the following:

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|----|---|-----------|-------------|-------------|----------------------|-------------------|
| 1 | Consider the impact of each of the following federal laws on the health care facility's pandemic preparedness plan. | | | | | |
| 1a | Americans with Disabilities Act, 42 U.S.C. § 12101 et seq. (2008) | | | | | |
| 1b | Fair Labor Standards Act, 29 U.S.C. § 201 et seq. (2008) | | | | | |
| 1c | Family and Medical Leave Act, 29 U.S.C. § 2601 et seq. (2008) | | | | | |
| 1d | National Labor Relations Act, 29 U.S.C. § 151 et seq. (2008) | | | | | |

F. STAFFING ISSUES - INITIAL PLANNING CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|----|---|-----------|-------------|-------------|----------------------|-------------------|
| 1e | Title VII of Civil Rights Act of 1964, 42 U.S.C. § 2000e et seq. (2008) | | | | | |
| 1f | Occupational Safety and Health Act, 29 U.S.C. § 651 et seq. (2008) | | | | | |
| 1g | Worker Adjustment and Retraining Notification Act, 29 U.S.C. 210l, et seq. (2008) | | | | | |
| 2 | Consider the impact of each of the following state laws on the health care facility's pandemic preparedness plan. | | | | | |
| 2a | Wage and Hour laws, N.J.S.A. § 34:11-56a et seq. (2008) and N.J.A.C. § 12:56 et seq. (2008) | | | | | |
| 2b | Workers' Compensation laws, N.J.S.A. § 34:15-1 et seq. (2008); N.J.S.A. § 34:15-43 (2008); N.J.A.C. § 12:235-1.1 et seq. (2008) | | | | | |
| 2c | Anti-Discrimination laws, N.J.S.A. § 10:5-12 (2008) | | | | | |
| 2d | Medical Leave laws, N.J.S.A. § 34:11B-1 et seq. (2008) | | | | | |

STAFFING ISSUES - INITIAL PLANNING

NEW JERSEY EXAMPLES

2. In the *New Jersey Influenza Pandemic Plan* (June 2008), the state estimates the following impacts of a pandemic on communities and in health care facilities:

“Depending on the severity of the disease, absenteeism is expected to reach 30%-50% in all sectors of the work force as the pandemic progresses. More specifically, widespread illness in communities will increase the likelihood of sudden and potentially significant shortages of personnel in sectors that provide critical community services (e.g., police, fire fighters, school staff, utility and transportation workers). In addition, shortages of health care workers are anticipated as they would be at higher risk of exposure and illness than the general population, which would further strain the health care system.”

...

“If a severe (1918-like) pandemic hits NJ, the impact on the health care system and the number of deaths are estimated as follows:

| | |
|---------------------------|---------------------------------------|
| Illness | 2,524,305 (30% of population) |
| Outpatient medical care | 1,262,152 (50% of ill) |
| Hospitalization | 277,668 (22% of outpatients) |
| ICU (Intensive Care Unit) | 41,825 (15% of hospitalized patients) |
| Mechanical ventilation | 20,825 (50% of ICU patients) |
| Deaths | 50,486 (2% of ill)” |

New Jersey Influenza Pandemic Plan (2008), Section III.B, “Impact on New Jersey.”

The *New Jersey Influenza Pandemic Plan* contains important information about the state's plans and guidance for addressing key health care facility staffing issues during a pandemic. Sections to review include, but are not limited to:

- Section VII.C "Health Care Planning"
- Section VII.D "Infection Control"
- Section VII.E "Vaccine Distribution and Use"
- Section VII.G "Antiviral Drug Distribution"
- Section VII.H "Community Disease Control and Prevention"
- Section VII.I "Public Health Communications"
- Section VII.J "Psychosocial Considerations"

(Available at: http://www.state.nj.us/health/flu/panflu_plan.shtml)

F. STAFFING ISSUES -- HEALTH CARE PROVIDER LICENSING STATUTES & REGULATIONS – MAXIMIZING DELEGABLE DUTIES

UNLICENSED PERSONNEL PERFORMING CLINICAL DUTIES

During a pandemic it may be necessary for non-clinical personnel to take on additional clinical duties that are not part of their daily practice. Health care facilities should determine how, if at all, to use non-clinical personnel for certain clinical duties in light of the 30-40 percent absenteeism rates predicted during a pandemic.

In your plan, consider the following:

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|---|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 1 | Identify the clinical activities that the health care facility would like to delegate to unlicensed personnel during a pandemic to mitigate the impact of staffing shortages. Consider activities like taking vital signs, assisting with toileting activities and transfers. | | | | | |
| 2 | Identify any statutes and regulations that allow or prohibit the clinical activities identified in Item 1 from being delegated to unlicensed personnel. | | | | | |
| 3 | Determine whether the health care facility's policies inhibit the ability to assign the clinical tasks identified in Item 1 to unlicensed personnel. | | | | | |

F. STAFFING ISSUES -- HEALTH CARE PROVIDER LICENSING STATUTES & REGULATIONS – MAXIMIZING DELEGABLE DUTIES CONTINUED

UNLICENSED PERSONNEL PERFORMING CLINICAL DUTIES

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|--|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 4 | Determine whether additional policies are necessary to allow the health care facility to delegate the activities identified in Item 1 to unlicensed personnel during a pandemic. | | | | | |
| 5 | Determine if there are any training programs that can be implemented in preparation for assigning the activities identified in Item 1 to unlicensed personnel. | | | | | |
| 6 | Consider the provision of “just in time” training for both infection control precautions in general and the clinical task itself. | | | | | |
| 7 | Determine how performance of these tasks by non-clinical personnel will be documented in the medical record. | | | | | |
| 8 | Identify those licensed providers who will be responsible for supervising the unlicensed personnel performing clinical tasks. | | | | | |

F. STAFFING ISSUES -- HEALTH CARE PROVIDER LICENSING STATUTES & REGULATIONS – MAXIMIZING DELEGABLE DUTIES CONTINUED

UNLICENSED PERSONNEL PERFORMING CLINICAL DUTIES

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|----|--|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 9 | Determine whether the licensed provider may be held liable for the acts or omissions of the unlicensed personnel and whether insurance coverage is available for this liability. | | | | | |
| 10 | Analyze whether the health care facility's insurance policies will cover any liabilities associated with unlicensed personnel performing clinical duties. | | | | | |

STAFFING ISSUES - HEALTH CARE PROVIDER LICENSING STATUTES & REGULATIONS – MAXIMIZING DELEGABLE DUTIES

UNLICENSED PERSONNEL PERFORMING CLINICAL DUTIES

NEW JERSEY EXAMPLES

2. The 2004 *Influenza Surge Capacity Guidance for General Hospitals* from the Office of the State Epidemiologist in the NJ Department of Health and Senior Services (“the guidance”) states that “[i]n the event that the hospital’s disaster plan has been activated, the facility should consider identifying a family member or friend of each inpatient to help with personal care of the patient, thus alleviating the need for hospital personnel to perform non-medical duties. These individuals must receive instruction in and practice infection control precautions.” To the extent that the guidance acknowledges that it may be appropriate for family or friends to help with the personal care of the patient, it is probably appropriate to task non-clinical hospital personnel with these tasks as well. The guidance does not specifically state that the hospital must provide this instruction, but that is the only logical inference. New Jersey health care facilities should consider planning for how they will provide this instruction at a time when staffing is already critically limited.

9. In New Jersey, the applicable supervising board may also revoke a license if the licensee permits an unlicensed person to perform an act for which a license is required (N.J.S.A. § 45:1-21(n) (2008)).

F. STAFFING ISSUES - HEALTH CARE PROVIDER LICENSING STATUTES & REGULATIONS – MAXIMIZING DELEGABLE DUTIES

SCOPE OF PRACTICE ISSUES INVOLVING LICENSED HEALTH CARE PRACTITIONERS

During a pandemic, it may be necessary for licensed health care practitioners to take on additional duties that are not part of their daily practice and that may either be outside the scope of duties permitted by the health care facility's policies and procedures, or even outside of the scope of practice as defined by relevant licensing laws. Health care facilities must determine how to use licensed personnel to the fullest extent by maximizing delegable duties, while avoiding placing these individuals and the patients to whom they provide care in harm's way.

In your plan, consider the following:

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|---|-----------|-------------|-------------|----------------------|-------------------|
| 1 | Identify how existing health care facility policies restrict providers' scope of practice. | | | | | |
| 2 | Determine whether the health care facility's policies are more restrictive than the statutory and regulatory scope of practice. | | | | | |
| 3 | Determine whether additional policies are necessary to allow the health care facility to maximize delegable duties during a pandemic. | | | | | |

F. STAFFING ISSUES - HEALTH CARE PROVIDER LICENSING STATUTES & REGULATIONS – MAXIMIZING DELEGABLE DUTIES CONTINUED

SCOPE OF PRACTICE ISSUES INVOLVING LICENSED HEALTH CARE PRACTITIONERS

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|--|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 4 | Understand the statutes and regulations that restrict a licensed provider’s scope of practice and any limitations on delegation of duties. | | | | | |
| 5 | Be familiar with each agency or board that is responsible for setting the scope of practice for each type of licensed health care provider in the health care facility. | | | | | |
| 6 | Identify the penalties for a licensed provider who practices outside his scope of practice. | | | | | |
| 7 | Determine what actions a licensed health care provider may be asked to perform during a pandemic that are not part of that provider’s normal activities and whether such actions are properly within the provider’s scope. | | | | | |

F. STAFFING ISSUES - HEALTH CARE PROVIDER LICENSING STATUTES & REGULATIONS – MAXIMIZING DELEGABLE DUTIES CONTINUED

SCOPE OF PRACTICE ISSUES INVOLVING LICENSED HEALTH CARE PRACTITIONERS

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|----|---|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 8 | Review the state’s Pandemic Influenza Response Plan to determine if it discusses the ability of providers to provide services that are not part of their normal activities. | | | | | |
| 9 | Determine if there are any training programs that can be implemented to bring actions identified in Item 7 into the provider’s scope of practice. Consider both training prior to a pandemic and “just in time” training. | | | | | |
| 10 | Assess whether requiring a provider to practice outside the scope of their license would constitute a liability risk under applicable state law. | | | | | |
| 11 | Identify mechanisms, if any, for modifying a type of provider’s statutory or regulatory scope of practice during a pandemic. See Emergency Health Powers Act and Emergency Services Laws, Section A and B of the Legal module.) | | | | | |

F. STAFFING ISSUES - HEALTH CARE PROVIDER LICENSING STATUTES & REGULATIONS – MAXIMIZING DELEGABLE DUTIES CONTINUED

SCOPE OF PRACTICE ISSUES INVOLVING LICENSED HEALTH CARE PRACTITIONERS

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|----|--|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 12 | Identify any penalties for a licensed provider who supervises another provider performing an action outside of the other provider's scope. | | | | | |
| 13 | Determine if and how reimbursement will be impacted if a licensed practitioner other than a physician performs an action typically performed by and billed by a physician. | | | | | |

STAFFING ISSUES - HEALTH CARE PROVIDER LICENSING STATUTES & REGULATIONS – MAXIMIZING DELEGABLE DUTIES

SCOPE OF PRACTICE ISSUES INVOLVING LICENSED HEALTH CARE PRACTITIONERS

NEW JERSEY EXAMPLES

2. In New Jersey, a properly trained physician assistant may, among other things, administer medications (N.J.A.C. § 13:35-2B.4(b)(2) (2008)). Some health care facilities in New Jersey may have policies that prevent a physician assistant from administering medications. This is an example of an area in which a facility policy is more restrictive than the actual laws governing the physician assistant's practice. During a pandemic, when staffing shortages are expected, the health care facility may want to revise its policies to allow a physician assistant to administer medications in accordance with applicable statutes and regulations.

4. The regulatory provisions related to scope of practice for licensed health care providers are contained in the following sections:

- Physicians' Assistants: N.J.A.C. § 13:35-2B.4 (2008).
- Nurses: N.J.S.A. § 45:11-49 (2008); N.J.A.C. §§ 8:43H-9.4 (2008); 13:37-6.1 et seq. (2008).
- Physical Therapists: N.J.A.C. § 13:39A-2.2 (2008).
- Occupational Therapists: N.J.A.C. § 13:44K-5.1 (2008).
- Respiratory Therapists: N.J.A.C. § 13:44F-3.1 (2008).

In New Jersey, registered professional nurses are responsible for all nursing care, including assessing nursing needs; planning nursing care; and implementing, monitoring and evaluating nursing plans. Registered professional nurses can delegate tasks to licensed practical nurses and other nursing personnel, including aides and assistants (N.J.A.C. § 13:37-6.2(a) (2008)). Registered professional nurses are responsible for supervising other nursing personnel after delegating tasks (N.J.A.C. § 13:37-6.2(c) (2008)). They are not allowed to delegate tasks to anyone who has not been properly trained, and they cannot delegate tasks that require a substantial degree of knowledge and skill (N.J.A.C. § 13:37-6.2(b)(1) (2008)) or an in-depth understanding of nursing principles, as this could result in harm to the patient (N.J.A.C. § 13:37-6.2(b)(2) (2008)).

5. The following boards regulate scope of practice for licensed health care providers in New Jersey:
- The New Jersey State Board of Medical Examiners is responsible for regulating the practice of physicians and podiatrists as well as overseeing the licensure and certification of acupuncturists, athletic trainers, electrologists, hearing aid dispensers, midwives, perfusionists, physician assistants (see generally N.J.S.A. § 45:9-1 et seq. (2008)).
 - The New Jersey Board of Nursing is responsible for regulating the practice of nurses, including licensed practical nurses and registered professional nurses. The New Jersey Board of Nursing also certifies advanced practice nurses and homemaker-home health aides (see generally N.J.S.A. § 45:11-23 et seq. (2008)).
 - The New Jersey State Board of Physical Therapy is responsible for regulating the practice of physical therapists (N.J.S.A. § 45:9-37.12 et seq. (2008)).
 - The Occupational Therapy Advisory Council is responsible for regulating the practice of occupational therapists (N.J.S.A. § 45:9-37.51 et seq. (2008)).
 - The State Board of Respiratory Care is responsible for regulating the practice of respiratory therapists (N.J.S.A. § 45:14E-1 et seq. (2008)).
6. New Jersey's Uniform Enforcement Act (N.J.S.A. § 45:1-1 et seq. (2008)) defines penalties for practicing outside the scope of practice and applies to every health care professional whose profession is regulated by a board (N.J.S.A. § 45:1-15 (2008)).

A board can suspend or revoke a health care provider's license if he/she engages in gross negligence; gross malpractice; gross incompetence that endangers a person's life or health (N.J.S.A. § 45:1-21(c) (2008)); or occupational misconduct as determined by the board (N.J.S.A. § 45:1-21(e) (2008)). The board may also revoke a license if the licensee permits an unlicensed person to perform an act for which a license is required (N.J.S.A. § 45:1-21(n) (2008)). Practicing outside of the licensee's scope of practice could be construed as gross malpractice or occupational misconduct.

Penalties for performing the actions listed above include, but are not limited to, a board-issued letter of warning, reprimand, or censure (N.J.S.A. § 45:1-22(a) (2008)); an order to undergo an assessment of skills to determine if the licensee is fit to continue practicing (N.J.S.A. § 45:1-22(g) (2008)); and/or an assessment of civil penalties (N.J.S.A. § 45:1-22(b) (2008)).

A health care professional who violates an act or regulation administered by his or her board can be liable for a civil penalty of not more than \$10,000 for the first violation and not more than \$20,000 for each subsequent violation (N.J.S.A. § 45:1-25(a) (2008)).

The Attorney General may bring an action against a licensee in the name of any board for collection or enforcement of civil penalties for violation of an act or regulation administered by the board. Process for this action may be by summons or warrant and, if the licensee fails to answer, the court may, after finding that the licensee committed an unlawful act, issue a warrant for the licensee's arrest (N.J.S.A. § 45:1-25(b) (2008)).

11. See Emergency Services Law, Section B of the Legal module related to the governor's ability to suspend or modify regulations during an emergency. In addition to the governor's power, each professional board has the power to issue emergency regulations under N.J.S.A. § 52:14B-4(c) (2008), which states "[i]f an agency finds that an imminent peril to the public health, safety, or welfare requires adoption of a rule upon fewer than 30 days' notice and states in writing its reasons for that finding, and the Governor concurs in writing that an imminent peril exists, it may proceed without prior notice or hearing, or upon any abbreviated notice and hearing that it finds practicable, to adopt the rule. The rule shall be effective for a period of not more than 60 days unless each house of the Legislature passes a resolution concurring in its extension for a period of not more than 60 additional days. The rule shall not be effective for more than 120 days unless repromulgated in accordance with normal rule-making procedures."

In a protracted event like a pandemic, a professional board may desire that its emergency regulation stay in effect for the duration of the event, which could be longer than 60 days. To do this, the board would have to obtain the approval of the Legislature, which may be difficult to secure during a public health emergency when social distancing is encouraged or required.

12. According to N.J.S.A. § 45:1-21(n) (2008), a board may suspend or revoke a licensee's license or certificate to practice if he/she has permitted an unlicensed person to perform an act for which a license or certificate is required, or aided and abetted an unlicensed person in performing such act.

F. STAFFING ISSUES - MEDICAL STAFF CONSIDERATIONS

Physician participation is crucial to a health care facility's ability to respond to any disaster, including a pandemic. While many of the scope of practice issues discussed under Tab E relate to physicians as well as other licensed providers in the health care facility, there are special considerations for physician participation during a pandemic related to privileging, credentialing and medical staff procedures. These must be understood and incorporated into preparedness plans to help ensure efficiency and effectiveness in the midst of a pandemic.

In your plan, consider the following:

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|--|---|-----------|-------------|-------------|----------------------|-------------------|
| EMERGENCY CREDENTIALING AND PRIVILEGING | | | | | | |
| 1 | Identify those statutes and regulations that may impact emergency credentialing and privileging. Consider the Emergency Health Powers Act; the Emergency Services Law; and laws and regulations regarding emergency administrative rule making. | | | | | |
| 2 | Consider the impact of these statutes and regulations on the ability of the health care facility to use in-state licensed providers who have retired or let their licenses lapse as part of a "surge" force. | | | | | |

F. STAFFING ISSUES - MEDICAL STAFF CONSIDERATIONS CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|--|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 3 | Consider the impact of these statutes and regulations on the ability of the health care facility to use out-of-state health care providers as part of a "surge" force. | | | | | |
| 4 | Develop policies and procedures for granting disaster privileges in accordance with Joint Commission requirements for emergency credentialing and privileging (HR 1.25). Consider plans related to assigning and overseeing disaster responsibilities and verification of licensure. | | | | | |
| 5 | Determine how, if at all, privileges for licensed providers may change if altered standards of care are implemented to handle resource shortages. | | | | | |
| 6 | Review, and modify if necessary, existing medical staff bylaws to ensure that they support the health care facility's emergency credentialing and privileging policies, as well as the expansion of privileges during altered standards of care. | | | | | |

F. STAFFING ISSUES - MEDICAL STAFF CONSIDERATIONS CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|--|---|-----------|-------------|-------------|----------------------|-------------------|
| ALTERED STANDARDS OF CARE (See Section G of the Legal module for a complete discussion.) | | | | | | |
| 7 | Identify how the health care facility will enforce medical staff compliance with an altered standard of care. | | | | | |
| 8 | Determine whether the medical staff bylaws should be amended to incorporate any altered standard of care compliance requirements or mechanisms. | | | | | |
| 9 | Discuss with the medical staff penalties for failure to comply with altered standards of care protocols. | | | | | |
| 10 | When thinking about enforcement and penalties, consider any statutes or regulations that allow a health care provider to abstain from the withdrawal of life saving measures. | | | | | |

STAFFING ISSUES - MEDICAL STAFF CONSIDERATIONS

NEW JERSEY EXAMPLES

Emergency Credentialing and Privileging

1. N.J.S.A. § 26:13-6 (2008) states “in the event the Governor declares a public health emergency, the commissioner may waive health care facility medical staff privilege requirements for individuals registered as emergency health care workers, and hospitals shall permit registered emergency health care workers to exercise privileges at the hospital for the duration of the public health emergency.” Health care facilities should consider their policies and procedures for incorporating these emergency health care workers into their emergency response plans. They should also consider whether these workers should be factored into their specific pandemic influenza response plans in light of the high potential for a lack of volunteers.

N.J.S.A. § 38A:20-4 et seq. (2008), the New Jersey Emergency Management Assistance Compact (NJEMAC), has a provision that waives professional licensure requirements for individuals licensed in another party state who are deployed to New Jersey pursuant to an EMAC request. See Volunteers, Section J of the Legal module.

2. N.J.S.A. § 45:9-6.1 (2008) requires every retired licensee to register biennially as a retired physician, and anyone who holds a certificate of registration is entitled to resume practice at any time. If an applicant for reinstatement of licensure has not practiced in any jurisdiction for more than five years, he/she may be required to pass an examination or assessment of skills before the license will be reinstated (N.J.S.A. § 45:9-6.1 (2008)). Providers may want to engage in discussions with the New Jersey State Board of Medical Examiners regarding reinstatement procedures during an emergency.

3. According to the Emergency Health Powers Act, during a public health emergency, the commissioner of NJDHSS may appoint out-of-state emergency health care providers (N.J.S.A. § 26:13-18(b)(1) (2008)), and/or waive state licensing requirements for health care providers from other jurisdictions (N.J.S.A. § 26:13-18(b)(2) (2008)). See also Example 1 above regarding NJEMAC. See also Emergency Services Law, Section B of the Legal module related to the governor’s ability to suspend or modify regulations during an emergency.

Altered Standards of Care

10. In New Jersey, a health care professional “may decline to participate in the withholding or withdrawing of measures utilized to sustain life, in accordance with his sincerely held personal or professional convictions. In such circumstances, the physician shall act in good faith to inform the patient and the health care representative, and the chief of the medical staff or other designated institutional official, of this decision as soon as practicable, to effect an appropriate, respectful and timely transfer of care, and to assure that the patient is not abandoned or treated disrespectfully” (N.J.S.A. § 26:2H-62 (2008)).

F. STAFFING ISSUES - PROVISION OF SCARCE COUNTERMEASURES TO HEALTH CARE FACILITY PERSONNEL

The term “countermeasures” is used to describe those actions and supplies that can be used to help protect individuals against infection with the pandemic influenza virus. Health care facilities will have some medical and non-medical countermeasures, like antiviral medications and personal protective equipment (PPE), available to protect its personnel against infection with the pandemic influenza virus. Despite the fact that many health care facilities are stockpiling antiviral medications and PPE, these countermeasures are likely to be limited in supply and will, therefore, have to be allocated according to a priority distribution list established by the facility. Providing a select group of personnel with a benefit that is not available to others causes understandable anxiety on the part of counsel. Care must be taken to assure that allocation decisions are based on objective criteria related to the ability of the health care facility to sustain operations so that it can respond to the pandemic.

In your plan, consider the following:

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|--|--|-----------|-------------|-------------|----------------------|-------------------|
| INITIAL PLANNING CONSIDERATIONS | | | | | | |
| 1 | Identify any federal or state prioritization schemes for countermeasures. | | | | | |
| 2 | Determine whether the health care facility has plans to allocate scarce medical and non-medical countermeasures. | | | | | |
| 3 | Develop a plan to allocate scarce medical and non-medical countermeasures if one does not exist. | | | | | |

F. STAFFING ISSUES - PROVISION OF SCARCE COUNTERMEASURES TO HEALTH CARE FACILITY PERSONNEL CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|--|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 4 | Determine how the health care facility plans to obtain its medical countermeasures. Consider sources such as the state cache, private health care facility stockpiles purchased with federal funds, private health care facility stockpiles purchased with the health care facility's private funds or some combination thereof. | | | | | |
| 5 | Review applicable federal restrictions on the use of medical countermeasures purchased with federal funds. Consider restrictions on when the countermeasures can be used and for what purposes (e.g., treatment of symptoms vs. prophylaxis). | | | | | |

F. STAFFING ISSUES - PROVISION OF SCARCE COUNTERMEASURES TO HEALTH CARE FACILITY PERSONNEL CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|--|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 6 | With respect to medical countermeasures, determine whether state prescription drug dispensing statutes and regulations may impact the health care facility's ability to dispense antiviral medications or vaccines to employees, their family members, or the medical staff during a pandemic, N.J.S.A. § 45:14-40 et seq. (2008). | | | | | |
| 7 | Presumably, the health care facility will only want to provide countermeasures to employees who agree to report to work during a pandemic. Consider how the health care facility will do this. | | | | | |
| 8 | If any employees are covered by collective bargaining agreements, review agreements to determine if the health care facility can require attendance in exchange for access to countermeasures. | | | | | |

F. STAFFING ISSUES - PROVISION OF SCARCE COUNTERMEASURES TO HEALTH CARE FACILITY PERSONNEL CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|--------------------------------|--|-----------|-------------|-------------|----------------------|-------------------|
| DISCRIMINATION ANALYSIS | | | | | | |
| 9 | Determine whether the allocation plan will withstand a discrimination allegation. | | | | | |
| 9a | Consider the criteria used to determine who receives the countermeasure and who does not, and determine whether any of these criteria violate federal anti-discrimination laws. See Staffing Issues Initial Planning, Section F of the Legal module. | | | | | |
| 9b | Consider the criteria used to determine who receives the countermeasure and who does not, and determine whether any of these criteria violate state anti-discrimination laws, N.J.S.A. § 10:5-12 (2008). | | | | | |

F. STAFFING ISSUES - PROVISION OF SCARCE COUNTERMEASURES TO HEALTH CARE FACILITY PERSONNEL CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---------------------------|---|-----------|-------------|-------------|----------------------|-------------------|
| 9c | Even if the allocation system is not discriminatory in the legal sense, evaluate the impact it will have on staff morale and public perception of the health care facility. | | | | | |
| COMMUNICATION PLAN | | | | | | |
| 10 | Develop a communication plan to transmit information to employees about countermeasures. | | | | | |
| 10a | Consider the content of the communications with respect to the need to use countermeasures and their potentially limited effectiveness. | | | | | |
| 10b | Consider the balance between informing employees and not frightening them. | | | | | |

F. STAFFING ISSUES - PROVISION OF SCARCE COUNTERMEASURES TO HEALTH CARE FACILITY PERSONNEL CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---------------------------------|---|-----------|-------------|-------------|----------------------|-------------------|
| LIABILITY CONSIDERATIONS | | | | | | |
| 11 | Consider any liability the health care facility could face for allocating countermeasures according to a scheme difference from that proposed by the federal or state government. | | | | | |
| 12 | Identify any liability that a health care facility could face if the countermeasures are unsuccessful and an employee becomes ill. | | | | | |
| 13 | Consider whether an employee who misuses the countermeasure, becomes ill, and sues the health care facility can be barred from recovery based on contributory negligence. | | | | | |
| 14 | Determine whether employees who are provided with countermeasures should be asked to sign a waiver of liability and whether it would be enforceable under state law. | | | | | |

F. STAFFING ISSUES - PROVISION OF SCARCE COUNTERMEASURES TO HEALTH CARE FACILITY PERSONNEL CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|-----|--|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 14a | Draft a waiver of liability, if appropriate. | | | | | |
| 14b | Determine whether such a waiver is enforceable under state law. | | | | | |
| 15 | Discuss with state government whether an emergency declaration could include liability protection for health care facilities that provide countermeasures, but employees still become ill. | | | | | |
| 16 | Understand the Public Readiness and Emergency Preparedness (PREP) Act, which is a part of the Department of Defense, Emergency Supplemental Appropriations to Address Hurricanes in the Gulf of Mexico, and Pandemic Influenza Act of 2006, Pub. L. 109-148. | | | | | |

F. STAFFING ISSUES - PROVISION OF SCARCE COUNTERMEASURES TO HEALTH CARE FACILITY PERSONNEL CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|--------------------------------|---|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 16a | Determine whether the PREP Act provides any liability protection for injuries caused by the countermeasures provided by the health care facility both before and during a pandemic. | | | | | |
| 16b | Be familiar with the declaration under the PREP Act designating the pandemic influenza A (H5N1) vaccine as a covered countermeasure, 72 FR 4710. | | | | | |
| EMPLOYEE FAMILY MEMBERS | | | | | | |
| 17 | Determine whether the health care facility will provide countermeasures to employees' family members. | | | | | |
| 18 | Determine whether the health care facility will charge family members for the countermeasures. | | | | | |

F. STAFFING ISSUES - PROVISION OF SCARCE COUNTERMEASURES TO HEALTH CARE FACILITY PERSONNEL CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|----|---|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 19 | Determine if the provision of medical countermeasures to employees' family members can be covered under the health care facility's health plan. | | | | | |
| 20 | Consider whether family members who receive countermeasures should sign a waiver of liability. | | | | | |
| 21 | Draft a waiver of liability, if appropriate. | | | | | |
| 22 | Determine whether such a waiver is enforceable in under state law. | | | | | |

STAFFING ISSUES - PROVISION OF SCARCE COUNTERMEASURES TO HEALTH CARE FACILITY PERSONNEL

NEW JERSEY EXAMPLES

1. Consider DHHS' *Interim Public Health Guidance for the Use of Facemasks and Respirators in Non-Occupational Community Settings During an Influenza Pandemic* (May 2007); OSHA's *Pandemic Influenza Preparedness and Response Guidance for Healthcare Workers and Healthcare Employers* (2007); and CDC's *Proposed Considerations for Antiviral Drug Stockpiling by Employers in Preparation for an Influenza Pandemic* (October 2007) and *Proposed Guidance on Antiviral Drug Use Strategies During an Influenza Pandemic* (November 2007).

The *New Jersey Influenza Pandemic Plan* contains important information about the state's plans and guidance for addressing the issues of scarce countermeasures. Sections to review include, but are not limited to:

- Section VII.C "Health Care Planning," which includes information about the state's plans for addressing obstacles to health care planning, including command and control of health care resources and allocation of scarce resources.
- Section VII.E "Vaccine Distribution and Use", which includes guidance on "the elements of a pandemic vaccination program," planning for distribution, tracking of supplies, adverse events reporting and legal preparedness.
- Section VII.G "Antiviral Drug Distribution," which includes the state's plans for its management of antiviral drugs from the Strategic National Stockpile, delivery to organizations responsible for local distribution and guidance for the use of antivirals.

(Available at: http://www.state.nj.us/health/flu/panflu_plan.shtml)

F. STAFFING ISSUES - EMPLOYEE SCREENING BY HEALTH CARE FACILITIES

During a pandemic, it will be important to ensure that personnel infected with the pandemic influenza virus do not report to work. To help ensure this, some health care facilities will screen employees at the beginning of each shift to identify symptoms or a history that would be suggestive of infection. Because the information collected during the screening is health information, it may be protected by state and federal privacy laws. These laws must be understood so that health care facilities can design screening programs that are compliant with applicable laws.

In your plan, consider the following:

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|-------------------------|--|-----------|-------------|-------------|----------------------|-------------------|
| INITIAL PLANNING | | | | | | |
| 1 | Determine the purpose(s) for employee screening. | | | | | |
| 2 | Determine the mechanism for employee screening. | | | | | |
| 2a | Identify the location and times for screenings. | | | | | |
| 2b | Identify those who will perform screenings (clinician vs. non-clinician; employed vs. contractor vs. volunteer; in-house vs. out-source; self-report). | | | | | |
| 2c | Determine whether and what type of training screeners will receive. | | | | | |

F. STAFFING ISSUES - EMPLOYEE SCREENING BY HEALTH CARE FACILITIES CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|----|---|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 2d | Determine what type of information will be collected during screenings (e.g., presence of physical symptoms and/or contact history). | | | | | |
| 2e | If the screener will inquire about contact history, determine what type of contact will trigger action (e.g., protected v. unprotected contact; close v. casual). | | | | | |
| 2f | Determine how screening records will be kept and for how long. | | | | | |
| 2g | Identify those actions that will be taken when a screener finds a symptomatic individual or an individual whose contact history suggests infection. | | | | | |
| 3 | Identify any state laws regarding an employer's ability to require a medical screening or examination of an employee and determine whether the health care facility's screening mechanism is compliant with these laws. | | | | | |

F. STAFFING ISSUES - EMPLOYEE SCREENING BY HEALTH CARE FACILITIES CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|--|--|-----------|-------------|-------------|----------------------|-------------------|
| PRIVACY OF INFORMATION COLLECTED DURING SCREENING | | | | | | |
| 4 | Determine whether information collected during the screening is protected health information (PHI) under HIPAA or state law. See HIPAA, Section D of the Legal module. | | | | | |
| 4a | Consider the method of collection – self-report vs. collection by a screener. | | | | | |
| 4b | If a screener is used, consider whether the screener is a clinician or a non-clinician, employed or not employed by the health care facility. | | | | | |
| 4c | Consider the type of information collected. | | | | | |
| 5 | If the information is PHI, consider whether a notice of privacy practices (NPP) will have to be delivered and consent will have to be obtained at the screening. | | | | | |
| 6 | If the information is PHI, consider whether there are any exceptions to HIPAA that are applicable to the use or disclosure of the information. | | | | | |

F. STAFFING ISSUES - EMPLOYEE SCREENING BY HEALTH CARE FACILITIES CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|----|--|-----------|-------------|-------------|----------------------|-------------------|
| 6a | Consider the exception that allows a covered entity to provide PHI to an employer regarding an employee, 45 CFR § 164.512(b)(1)(v) (2008). | | | | | |
| 6b | Consider HIPAA exceptions discussed in Section D of the Legal module. | | | | | |
| 7 | Determine whether the information collected during the screening is protected under state privacy and confidentiality laws. | | | | | |
| 8 | Analyze the use and disclosure of screening information to ensure compliance with HIPAA, if applicable, as well as applicable state laws. | | | | | |
| 9 | Even if the information is not protected under state or federal law, determine whether it is personal information that should be given the same level of confidentiality that is given to other personnel records. | | | | | |

F. STAFFING ISSUES - EMPLOYEE SCREENING BY HEALTH CARE FACILITIES CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|--|--|-----------|-------------|-------------|----------------------|-------------------|
| LIABILITY ASSOCIATED WITH SCREENING | | | | | | |
| 10 | Analyze the health care facility's liability for "under screening" – failing to identify an infected person when it should have detected the infection. | | | | | |
| 11 | Analyze the health care facility's liability for "over screening" – categorizing a person as infected when they are not. Consider liability associated with defamation and lost wages. | | | | | |
| 12 | Consider whether outsourcing screening services may mitigate liability for the health care facility. | | | | | |

STAFFING ISSUES - EMPLOYEE SCREENING BY HEALTH CARE FACILITIES

NEW JERSEY EXAMPLES

Initial Planning

3. N.J.S.A. § 34:11-24.1 (2008) contains requirements related to medical examinations requested by employers. Specifically, it provides that “[n]o employer or prospective employer shall deduct from the wages of any employee or from the wages to be paid to a prospective employee any sum, or in any manner require payment of any sum from such employee or prospective employee, to defray the cost of any medical examination of such employee or prospective employee when such examination is made at the request or direction of the employer, by a physician designated by said employer, as a condition of entering or continuing employment, and in the event that the employee or prospective employee pays for any such medical examination, the employer or prospective employer shall reimburse the employee or prospective employee for the amount of any such payment.”

F. STAFFING ISSUES - LEGAL CONSIDERATIONS RELATED TO CONTRACTORS

Until very recently, physicians practicing in health care facilities were independent contractors. Health care facilities increasingly employ physicians today, but many physicians remain in private practice with contracts to provide specific services at the health care facility. This contractual relationship is often desirable because it affords physicians a certain degree of freedom that they would not have as employees of the facility. During a pandemic, however, this status may pose certain challenges for both the health care facility and the contractor that must be appreciated and taken into account in pandemic preparedness plans.

In your plan, consider the following:

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|--|-----------|-------------|-------------|----------------------|-------------------|
| 1 | Identify those health care facility personnel who are contractors and what services they provide. | | | | | |
| 2 | Determine whether a contractor's services will be needed during a pandemic. Consider that some elective services will likely be suspended during a pandemic, at least for part of the event. | | | | | |
| 3 | To the extent that a contractor does not work exclusively for the health care facility, determine whether his/her duties at the health care facility will take precedence over his/her other obligations during a pandemic. If the health care facility desires such precedence, consider amending the contractor's agreement to require it. | | | | | |

F. STAFFING ISSUES - LEGAL CONSIDERATIONS RELATED TO CONTRACTORS CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|---|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 4 | Review all contractor agreements to determine whether there are any provisions that clearly require a contractor to continue providing services in the event of a pandemic at the discretion of the health care facility. If these provisions do not exist, consider amending the agreements to incorporate them. | | | | | |
| 5 | Identify any provisions in contractor agreements that would provide an excuse for non-performance. | | | | | |
| 6 | Evaluate if a contractor's compensation can be reduced if it is a monthly fixed fee and the contractor fails to perform all services. | | | | | |
| 7 | Evaluate the health care facility's potential liability if a contractor is infected while performing services at the health care facility. Consider liability under the terms of the agreement and the potential non-applicability of workers' compensation. | | | | | |

F. STAFFING ISSUES - LEGAL CONSIDERATIONS RELATED TO CONTRACTORS CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|---|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 8 | To the extent that contractors will be asked to serve on triage committees or otherwise allocate scarce resources, determine whether they are covered by the health care facility's insurance policy. See Altered Standards of Care, Section G of the Legal module. | | | | | |
| 9 | If it is determined that contractors are not covered for their roles on triage committees or for the allocation of scarce resources, consider whether it is advisable or desirable to offer incentives to contractors by ensuring that they are so covered. | | | | | |

F. STAFFING ISSUES - EMPLOYEE ASSISTANCE PROGRAMS

Employee Assistance Plans (EAPs) are often part of employee health plans. Employees will expect these services to be available during an emergency. Health care facilities must consider whether and to what extent these services may be continued during an emergency.

In your plan, consider the following:

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|--|-----------|-------------|-------------|----------------------|-------------------|
| 1 | Identify if and to what extent Employee Assistance Programs (EAPs) will be available during a pandemic or other public health emergency. | | | | | |
| 2 | Identify how EAPs will be staffed during a pandemic. Consider whether the health care facility will use its employees or a vendor. | | | | | |
| 3 | Identify if the existing contracts with EAP providers have provisions that address emergencies. | | | | | |
| 4 | Determine if the existing EAP agreements give the health care facility priority during a pandemic. | | | | | |
| 5 | Amend EAP contracts to add language that ensures continued services and gives the health care facility priority during a pandemic. | | | | | |

F. STAFFING ISSUES - EMPLOYEE ASSISTANCE PROGRAMS CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|---|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 6 | Identify alternate or additional EAP providers to ensure coverage to health care facility staff during pandemics. | | | | | |

STAFFING ISSUES - EMPLOYEE ASSISTANCE PROGRAMS

NEW JERSEY EXAMPLES

1. The *New Jersey Influenza Pandemic Plan* (June 2008), Section VII.J. "Psychosocial Considerations" includes information about the state's plans and support services available to "help response workers and the public manage emotional stress during and after a pandemic" (available at: http://www.state.nj.us/health/flu/panflu_plan.shtml).

F. STAFFING ISSUES - **INFRASTRUCTURE FOR DECISION MAKING DURING DISASTERS**

Health care facilities should have in place an effective incident command structure to be used in the event of an emergency. In 2004, the Department of Homeland Security released the National Incident Management System (NIMS) as required by Homeland Security Presidential Directive (HSPD) 5-Management of Domestic Incidents and HSPD-8 Preparedness. NIMS provides a consistent nationwide template for federal, state, tribal and local governments and private sector/nongovernmental organizations to work together effectively and efficiently to prepare for, prevent, respond to, and recover from domestic incidents, regardless of cause, size or complexity, including acts of catastrophic terrorism. NIMS benefits include a unified approach to incident management; standard command and management structures; and emphasis on preparedness, mutual aid and resource management.*

* = Excerpted from *NIMS Compliance – Overview* available at: <http://www.fema.gov/emergency/nims/faq/compliance.shtm> .

In your plan, consider the following:

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|---|-----------|-------------|-------------|----------------------|-------------------|
| INCIDENT COMMAND STRUCTURE (ICS) | | | | | | |
| 1 | Determine if the health care facility has an infrastructure in place for decision making during pandemics (i.e., an ICS). | | | | | |
| 2 | While operating under ICS, certain individuals will be vested with decision making authority. Identify and assess the types of potential liability to which these individuals may be exposed. | | | | | |

F. STAFFING ISSUES - INFRASTRUCTURE FOR DECISION MAKING DURING DISASTERS
CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|------------------------|---|-----------|-------------|-------------|----------------------|-------------------|
| 3 | <p>Determine if there are any liability protections available for those making decisions under ICS, including:</p> <ul style="list-style-type: none"> • Malpractice or other liability insurance through the employer; • Indemnification by employer; • Sovereign immunity through the state; and/or • Any other statutory or common law liability protections. | | | | | |
| 4 | <p>Identify and assess the potential consequences and liabilities if an employee fails to follow the ICS and as a result causes harm. Consequences and liabilities may include:</p> <ul style="list-style-type: none"> • Liability through the employer (e.g. termination or reprimand); • Civil liability; and/or • Criminal liability. | | | | | |
| NIMS COMPLIANCE | | | | | | |
| 5 | <p>(See generally http://www.fema.gov/emergency/nims/compliance/assist_non_govt.shtm)</p> <p>Determine whether the health care facility is required to be NIMS compliant because it receives federal preparedness and response grants, contracts or cooperative agreements.</p> | | | | | |
| 6 | <p>If the health care facility is required to be NIMS compliant, assess whether it has completed the NIMS activities that were required as of September 30, 2007.</p> | | | | | |

F. STAFFING ISSUES - INFRASTRUCTURE FOR DECISION MAKING DURING DISASTERS
CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|----|--|-----------|-------------|-------------|----------------------|-------------------|
| 7 | If the health care facility is required to be NIMS compliant, assess whether it has or will complete the activities that are required as of September 30, 2008. | | | | | |
| 8 | Determine whether the health care facility has maintained sufficient documentation related to required NIMS training. | | | | | |
| 9 | If the health care facility is not NIMS compliant, but is required to be, determine what aspects are deficient and identify the reasons for the deficiencies. | | | | | |
| 10 | Identify the penalties for failing to be NIMS compliant. See Health Care Facility Licensure and Regulatory Issues, Pandemic Influenza Spending Guidelines and Compliance, Section C of the Legal module. | | | | | |
| 11 | Identify whether failing to be NIMS compliant has any impact on the health care facility's reimbursement from federal payers (e.g., Medicare, Medicaid, CHAMPUS). | | | | | |
| 12 | Understand the relationship between NIMS and the Hospital Incident Command System (HICS). | | | | | |

G. ALTERED STANDARDS OF CARE - INITIAL PLANNING

Most people in the health care sector recognize that, during a pandemic, health care providers will not be able to provide care at the level at which we are accustomed today. Providers will have to limit care with a focus on providing the greatest good for the greatest number of people, rather than providing individual based care. This limiting of care is often referred to as an “altered standard of care.” Not only is the use of this term controversial in its own right, the concept of altered standards of care is difficult for health care providers to accept, and may create conflict during an emergency when the health care facility and staff need to work together to care for patients. Health care facilities must plan now for the implementation of altered standards of care during emergencies, like a pandemic.

In your plan, consider the following:

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|--|-----------|-------------|-------------|----------------------|-------------------|
| 1 | Determine whether the health care facility has started planning for the development and implementation of altered standards of care. | | | | | |
| 2 | Communicate with the state health department to determine whether they have created, or are in the process of creating, guidance regarding altered standards of care. | | | | | |
| 3 | Communicate with the state's hospital association to determine whether they have created, or are in the process of creating, guidance regarding altered standards of care. | | | | | |

G. ALTERED STANDARDS OF CARE - INITIAL PLANNING CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|----------------------------------|---|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 4 | Review the available literature on altered standards of care. See Appendix E. | | | | | |
| PRE-PANDEMIC PREPAREDNESS | | | | | | |
| 5 | Develop policies and procedures to address altered standards of care preparedness, response and recovery. See <i>Critical Resource Shortages: A Planning Guide</i> within Appendix F. | | | | | |
| 6 | Identify an existing committee(s), or establish a new committee, that will be responsible for conducting a critical resource vulnerability analysis and establishing baseline principles that will be used when determining how to respond to a critical resource shortage. | | | | | |
| 7 | Conduct a critical resource vulnerability analysis to determine which critical resources may become limited in the event of a pandemic. | | | | | |

G. ALTERED STANDARDS OF CARE - INITIAL PLANNING CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|----|--|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 8 | Establish baseline ethical principles to guide the response to critical resource shortages and the development of specific critical resource shortage response plans. | | | | | |
| 9 | Address key operational issues to guide the development of specific critical resource shortage response plans. | | | | | |
| 10 | Develop critical resource shortage response plans to address the resources (e.g., material resources, physical space, and personnel) identified in the critical resource vulnerability analysis according to the prioritization determined by the committee established in Item 6. | | | | | |
| 11 | Develop triage protocols that will be used in a pandemic. | | | | | |
| 12 | Create a decision making process should the hospital need to allocate resources that have not been addressed in pre-event plans. | | | | | |

G. ALTERED STANDARDS OF CARE - INITIAL PLANNING CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|---|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 13 | Modify the emergency operations plan and incident command structure to reflect the incorporation of critical resource shortage response plans (including operational considerations; ethical principles; pre-existing plans; and mechanisms for the creation of ad hoc plans) and triage protocols. | | | | | |
| 14 | Educate medical staff and health care facility personnel on the development and implementation of critical resource shortage response plans. | | | | | |
| 15 | Conduct exercises and drills to test the critical resource shortage response plans. | | | | | |
| RESPONSE DURING A PANDEMIC EVENT | | | | | | |
| 16 | Report a critical resource shortage through established ICS procedures. | | | | | |
| 17 | Determine whether there is a pre-existing critical resource shortage response plan to address the resource in question. | | | | | |

G. ALTERED STANDARDS OF CARE - INITIAL PLANNING

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|----|--|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 18 | Develop an ad hoc critical resource shortage response plan for resources (e.g., material resources, physical space, personnel) that become scarce during the pandemic and for which a response plan was not created during pre-event planning. | | | | | |
| 19 | Implement the critical resource shortage response plan (pre-existing or ad hoc) for the resource that is scarce. | | | | | |
| 20 | Modify the critical resource shortage response plan as needed throughout the event. | | | | | |
| 21 | Terminate the critical resource shortage response plan when resource levels have returned to normal. | | | | | |
| 22 | Provide psychological support services to employees, staff and physicians. | | | | | |
| 23 | Provide support and recovery services to patients and their families. | | | | | |

G. ALTERED STANDARDS OF CARE - INITIAL PLANNING

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|--|--|-----------|-------------|-------------|----------------------|-------------------|
| RECOVERY AFTER A PANDEMIC EVENT | | | | | | |
| 24 | Provide psychological support services to employees, staff and physicians. | | | | | |
| 25 | Evaluate the use and effectiveness of critical resource shortage response plans and processes. | | | | | |
| 26 | Modify plans and processes as appropriate based on actual experiences during the event. | | | | | |
| 27 | Provide support and recovery services to patients and their families. | | | | | |

ALTERED STANDARDS OF CARE - INITIAL PLANNING

NEW JERSEY EXAMPLES

2. The *New Jersey Influenza Pandemic Plan* (June 2008), Section VII.C. "Health Care Planning" includes information about the state's plans for addressing obstacles to health care planning, including altered standards of care (and attendant liability issues) and the allocation of scarce resources (available at: http://www.state.nj.us/health/flu/panflu_plan.shtml).

G. ALTERED STANDARDS OF CARE - LIABILITY

The concept of altered standards of care causes concern among health care providers for many reasons, including a fear of liability for not providing care as it is customarily provided. Litigation post-SARS and post-Hurricane Katrina have raised legitimate concerns about how a health care facility's conduct during a pandemic will be judged after the fact. Providers and counsel must understand the real liability risks associated with rationing scarce resources during an emergency or disaster to ensure that altered standards of care planning moves forward effectively.

In your plan, consider the following:

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|----|--|-----------|-------------|-------------|----------------------|-------------------|
| 1 | Understand the state's statutory standard of care in medical malpractice actions. | | | | | |
| 1a | Identify the relevant statutes. | | | | | |
| 1b | Determine whether the statutory standard of care is local, statewide or national. | | | | | |
| 1c | Determine whether the statutory standard of care requires the jury to consider the circumstances under which the care was provided. | | | | | |
| 1d | If the statute does not contemplate the circumstances of care, identify relevant case law that interprets whether and how circumstances should be acknowledged, or how the jury may weigh these circumstances. | | | | | |

G. ALTERED STANDARDS OF CARE – LIABILITY CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|----|---|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 1e | Identify any case law that has interpreted the standard of care in disasters. | | | | | |
| 1f | Determine whether a pandemic event or resource shortage may be considered in determining whether a provider met the standard of care. | | | | | |
| 2 | Determine whether the state attorney general has issued any rulings related to changes in the standard of care during an emergency. | | | | | |
| 3 | Identify the model jury instructions regarding the standard of care in medical malpractice actions. | | | | | |
| 3a | Determine whether these instructions accurately reflect and are consistent with the statute. | | | | | |
| 3b | Evaluate whether the instructions require the jury to consider the circumstances under which the care was provided. | | | | | |

G. ALTERED STANDARDS OF CARE – LIABILITY CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|----|--|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 4 | Explore whether there are state statutes that provide liability protection to health care providers rendering care in the face of scarce resources during an emergency, including a pandemic. | | | | | |
| 4a | Consider the applicability of any statutes that bring health care providers under the auspices of the state government and thus entitle them to sovereign immunity. | | | | | |
| 4b | Consider the applicability of "Good Samaritan" laws. See Volunteers, Section J of the Legal module. | | | | | |
| 4c | Consider any immunity provided by the Emergency Services Law and Emergency Health Powers Act. See Emergency Health Powers Act and Emergency Services Laws, Sections A and B of the Legal module. | | | | | |
| 5 | Examine existing managed care contracts to determine whether provision of care under an altered standard during a pandemic creates breach of contract issues. | | | | | |

G. ALTERED STANDARDS OF CARE – LIABILITY CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|--|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 6 | Determine whether the health care facility's directors and officers insurance policy covers decisions made by triage committees or triage officers with respect to the allocation of scarce resources. | | | | | |
| 7 | If directors and officers coverage exists for decisions made by triage committees or triage officers, determine whether contracted physicians are covered by such policy. | | | | | |

ALTERED STANDARDS OF CARE - LIABILITY

NEW JERSEY EXAMPLES

1a. There is no *statutory* standard of care for medical malpractice in New Jersey. The Supreme Court of New Jersey holds that “[a] physician must act with that degree of care, knowledge, and skill ordinarily possessed and exercised in similar situations by the average member of the profession practicing in the field” (*Velazquez v. Portadin*, 163 N.J. 677, 686, 751 A.2d 102 (2000)). Further, there is a statutory requirement that, in a medical malpractice case, the plaintiff file an affidavit by an appropriately licensed person stating that there exists a reasonable probability that the care, skill or knowledge exercised in the treatment fell outside acceptable professional standards or treatment practices (N.J.S.A. § 2A:53A-27 (2008)).

1b. Based on the case law cited in 1a, it appears that the standard of care in New Jersey is statewide. Legal counsel for the health care facility should confirm the state of the law during a pandemic.

1c. In New Jersey, there is no statutory standard of care and the New Jersey Supreme Court does not explicitly indicate that the standards applied in medical malpractice actions account for a specific set of circumstances.

2. As of June 13, 2008, a search of New Jersey Attorney General Opinions did not return any opinions on point.

3a. The relevant model jury instructions in New Jersey can be found in *Model Jury Charge (Civil)* § 5.50 A Duty and Negligence (March 2002) available at: <http://www.judiciary.state.nj.us/civil/charges/> .

3b. New Jersey’s general model jury charge on medical negligence and standard of care states that “[t]he determination of whether a defendant was negligent requires a comparison of the defendant’s conduct against a standard of care” (*Model Jury Charge (Civil)* § 5.50 A Duty and Negligence (March 2002)). The charge then explains that the defendant is a member of a profession and that “to decide this case properly you must know the standard of care...against which the defendant’s conduct as a [member of that profession] should be measured.” *Id.* The charge provides options for a specialist and a general practitioner. Option A explains that a specialist has a duty “to have and to use that degree of knowledge and skill which is normally possessed and used by the average specialist in that field.” *Id.* Option B notes that a general practitioner “represents that he/she . . . will have and employ knowledge and skill normally possessed and used by the average physician practicing his/her profession as a general practitioner.” *Id.*

The New Jersey general model jury charges on medical negligence reference the circumstances of the case, but do not elaborate on which circumstances should be considered and how they should be weighted (Model Jury Charge (Civil) §§ 5.50 A and B (March 2002)).

4. New Jersey provides limited immunity for non-profit corporations organized exclusively for hospital purposes (N.J.S.A. § 2A:53A-7 (2008)), but a health care facility's agents, employees or servants are not similarly immunized.

There are also a number of sections of the New Jersey Code that provide immunity for those providing health and medical services in certain situations. For example, N.J.S.A. § 2A:62A-1.3 (2008) provides immunity from civil liability for certain health care professionals. The statute states, “[i]f an individual's actual health care facility duty, including on-call duty, does not require a response to a patient emergency situation, a health care professional who, in good faith, responds to a life-threatening emergency or responds to a request for emergency assistance in a life-threatening emergency within a hospital or other health care facility, is not liable for civil damages as a result of an act or omission in the rendering of emergency care.” This statute would most likely not be applicable to care provided under altered standards in the face of resource shortages because the health care providers giving such care will be doing so within their duties and for compensation.

4a. There does not appear to be a specific provision that brings health care facilities or health care workers under the auspices of the state, thus allowing them to take advantage of sovereign immunity. New Jersey has waived sovereign immunity for itself and its counties, municipalities and other political subdivisions to the extent set forth in the New Jersey Tort Claims Act (N.J.S.A. § 59:1-1 (2008)). Public entities and public employees retain immunity from liability for various acts including: (1) failure to provide a medical facility or mental institution; (2) failure to provide sufficient equipment, personnel or facilities in a mental institution or medical facility; (3) a decision to perform or not to perform any act to promote the public health of the community; and (4) failure to make an adequate physical or mental examination of any person for the purpose of determining whether such person has a disease or physical or mental condition that would constitute a hazard to the health or safety of him/herself or others, unless such examination or diagnosis was for the purpose of treatment (N.J.S.A. §§ 59:6-2 to 59:6-5 (2008)). Health care facilities and health care providers should consider whether coming under the auspices of the state for sovereign immunity purposes is advisable or feasible. Health care facilities should also review the state's Emergency Health Powers Act, Emergency Services Laws and state governmental response plans to determine if the state will incorporate health care facilities or workers into the “state forces” eligible for immunity of other liability protections.

G. ALTERED STANDARDS OF CARE - WITHDRAWAL OF CARE

As altered standards of care protocols are developed, some may call for withdrawing a scarce resource from a patient to give to another patient who may receive greater benefit from the resource. Other protocols may require the withholding of a resource from a patient who has little chance for benefit. For many providers, the idea of withdrawing care once it has been started is ethically difficult. Providers and counsel should be familiar with statutes and regulations surrounding withdrawal of care, to the extent that this will be part of an altered standard during a pandemic.

In your plan, consider the following:

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|----|---|-----------|-------------|-------------|----------------------|-------------------|
| 1 | Identify any federal or state resources or guidance documents that address the withdrawal of care. | | | | | |
| 2 | Determine whether there are any statutes, regulations or case law that would prohibit a health care provider from withdrawing a resource from one patient, without his/her consent, to give to another patient (e.g., ventilator) based upon some objective criteria. | | | | | |
| 2a | Consider informed consent laws and patient abandonment laws. | | | | | |
| 2b | Consider criminal laws (e.g., voluntary manslaughter). | | | | | |

G. ALTERED STANDARDS OF CARE - WITHDRAWAL OF CARE CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|----|---|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 2c | Evaluate whether any health care facility policies and procedures need to be amended in contemplation of withdrawal of resources from a patient during a resource shortage. | | | | | |
| 3 | Identify any laws regarding a duty to provide care to infectious patients, and determine if these laws can be construed to prohibit the withdrawal of a resource from an infectious patient. | | | | | |
| 4 | Identify any laws that would prohibit health care facilities from sanctioning employees who refuse to comply with orders to allocate scarce resources. See Staffing Issues Medical Staff Considerations, Section F of the Legal module. | | | | | |

ALTERED STANDARDS OF CARE - WITHDRAWAL OF CARE

NEW JERSEY EXAMPLES

2. There are no statutes or regulations that are directly on point. N.J.A.C. § 8:43G-4.1 (2008) does, however, recognize the right of patients “[t]o be informed of the hospital’s policies and procedures regarding life-saving methods and the use or withdrawal of life-support mechanisms.” This requirement could be construed to require a health care facility to inform its patients about the implementation of altered standards of care to the extent that such standards will require the withdrawal of life-support mechanisms.

2a. N.J.S.A. § 26:2H-12.8d (2008) states that hospital patients have the right to “receive from the physician information necessary to give informed consent prior to the start of any procedure or treatment.” The information should “include as a minimum the specific procedure or treatment, the medically significant risks involved, and the possible duration of incapacitation, if any, as well as an explanation of the significance of the patient’s informed consent.” The statute goes on to state that the “patient shall be advised of any medically significant alternatives for care or treatment, however, this does not include experimental treatments that are not yet accepted by the medical establishment.” *Id.* The statute does not directly address consent for the withdrawal of treatment. To the extent, however, that withdrawal of one treatment leads to implementation of another, informed consent would be required for the implementation. Please note that informed consent is not required in “emergency situations” (N.J.S.A. § 26:2H-12.8d (2008)).

N.J.S.A. § 26:2H-12.8b (2008) adds that the patient also has the right to be informed of the name of the physician responsible for coordinating the care. If, as part of the health care facility’s altered standards of care protocols, a triage officer will be utilized, the patient should be notified about the identity of the triage officer since he will be coordinating the patient’s care.

3. In New Jersey, there do not appear to be any laws (statutory or administrative) that explicitly describe a provider’s duty toward infectious patients.

H. CONTRACT ISSUES - INITIAL PLANNING

Health care facilities have various contractual obligations to employees, supply vendors, utility providers, third party payers and lenders that will have to be met during an emergency. Health care facilities should begin to review these agreements for provisions that address emergencies, and consider amending these agreements to add emergency specific provisions that will ensure the facility can continue to provide services during an emergency and remain in good standing with vendors, payers, providers and lenders.

In your plan, consider the following:

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|---|-----------|-------------|-------------|----------------------|-------------------|
| 1 | Identify the various contracts and agreements to which the health care facility is a party. | | | | | |
| 2 | Understand that a pandemic is predicted to occur in multiple waves over a period of 12 to 18 months, so contracts for a wide variety of goods and services are "critical." | | | | | |
| 3 | Review state laws and regulations for provisions that address suspension of a healthcare facility's, healthcare provider's or third party payer's obligation to meet certain contract provisions during a pandemic. | | | | | |

H. CONTRACT ISSUES - **INITIAL PLANNING CONTINUED**

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|--|-----------|-------------|-------------|----------------------|-------------------|
| 4 | Identify individuals at the health care facility who will be responsible for ensuring contractors meet their contractual obligations to the facility, as well as the facility meeting its contractual obligations during a pandemic. | | | | | |

H. CONTRACT ISSUES - SUPPLY VENDORS

Health care facilities have various agreements with vendors to provide supplies and services. Timely and reliable delivery of supplies and services is essential to health care facility operations. During an emergency, vendors will face many of the same problems related to staffing, logistics and access to supplies that health care facilities will face. Health care facilities must evaluate their vendor agreements now, and amend them as needed, to ensure that the facility will continue to receive goods and services during an emergency.

In your plan, consider the following:

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|--|-----------|-------------|-------------|----------------------|-------------------|
| 1 | Identify any provisions in contracts with vendors that may be applicable to a pandemic or emergency scenario. | | | | | |
| 2 | Identify any provisions in vendor contracts that would either require the vendors to continue performance during a pandemic, or provide them with an excuse for non-performance. | | | | | |
| 3 | Determine what, if any, legal recourse the health care facility would have if a supplier fails to deliver supplies during a pandemic. Consider emergency services laws, the terms of the contract and any applicable state laws. | | | | | |

H. CONTRACT ISSUES - SUPPLY VENDORS CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|--|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 4 | Assess whether the health care facility has legal recourse against vendors who fail to perform during a pandemic. Consider the reason for failure to perform (e.g., closed roads vs. vendor's employees do not want to deliver to the health care facility during a pandemic); this may affect the legal recourse available. | | | | | |
| 5 | Identify any MOUs that the health care facility has entered into with other health care facilities related to regional sharing or allocation of supplies during a pandemic. | | | | | |
| 6 | Determine if any of the supply MOUs are applicable during a pandemic. | | | | | |
| 7 | Because the health care facility may experience disruption in reimbursement during a pandemic, determine if the health care facility can amend its agreements with vendors to allow for delayed payment during a pandemic. | | | | | |

H. CONTRACT ISSUES - SUPPLY VENDORS CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|----|--|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 8 | Identify or create contract language that requires vendors to continue performing, even if the health care facility cannot pay in accordance with the contractual payment terms during a pandemic. | | | | | |
| 9 | Determine if the health care facility has any legal duty to protect the health of vendors who come to the health care facility to deliver supplies during a pandemic. | | | | | |
| 10 | Determine if the health care facility has a duty to inform vendors of the potential risks associated with making deliveries to the health care facility during a pandemic. | | | | | |
| 11 | Identify procedures and practices that could minimize the risks to vendors making deliveries to the health care facility during a pandemic. | | | | | |
| 12 | Identify the impact on a vendor's obligation to perform if the health care facility has been quarantined or is located within an area that has been quarantined. | | | | | |

CONTRACT ISSUES - SUPPLY VENDORS

NEW JERSEY EXAMPLES

9. and 10. Health care facilities should review with legal counsel whether the health care facility or its medical staff have any duty to protect vendors coming to the health care facility during a pandemic, or to inform them about the potential risks associated with making a delivery to the health care facility during a pandemic. Arguably, if there is a declared public health emergency, vendors and the public will be aware of the pandemic or other emergency, and will have received messages from government about the risks associated with the emergency.

Health care facilities should identify procedures and practices that could minimize the risks to vendors making deliveries to the health care facility during a pandemic, and consult with legal counsel to ensure that these procedures are documented.

H. CONTRACT ISSUES - UTILITIES

Power, water, sewer, telephone, intranet and internet services are essential to health care facility operations; however, facilities are not in control of the continued sustainability of these critical services. Health care facilities must plan now to ensure continuation of these services during an emergency to ensure they can continue to provide safe health care services. Careful examination of contracts with the public and private entities that provide these services, and the related legal issues, is a vital part of a health care facility's emergency planning.

In your plan, consider the following:

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|--|-----------|-------------|-------------|----------------------|-------------------|
| 1 | Identify how the health care facility will maintain utility services during a pandemic. | | | | | |
| 2 | Determine if the health care facility will likely need to expand any of its utility services during a pandemic, such as expanding the number of telephone lines to accommodate a dramatically increased call volume or increasing the health care facility's internet capabilities if employees will be telecommuting. | | | | | |
| 3 | Once the utilities requiring surge capacity during a pandemic have been identified, the health care facility should engage in discussions and negotiate agreements now with those utilities to provide for that surge capacity. | | | | | |

H. CONTRACT ISSUES – UTILITIES CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|--|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 4 | Determine if the health care facility will be liable for failure to sustain operations due to the lack of essential utilities during a pandemic. Conduct an analysis for each utility the health care facility uses. | | | | | |
| 5 | Determine if the health care facility's potential liability for failure to sustain operations due to the lack of essential utilities during a pandemic will be mitigated if the health care facility has a plan for the utility failure. | | | | | |
| 6 | Determine if the liability for utility failure depends on whether the health care facility has exhausted its plan for the utility failure (e.g., used all five days worth of bottled water reserve and is in day six of a water shortage). | | | | | |
| 7 | Determine if the health care facility has any written contracts with utility companies for the provision of services. | | | | | |

H. CONTRACT ISSUES – UTILITIES CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|----|--|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 8 | Identify any provisions in contracts with utilities that would either require the utilities to continue performance during a pandemic, or provide them with an excuse for non-performance. | | | | | |
| 9 | Determine whether the health care facility has any recourse against the utility company for failure to provide services. | | | | | |
| 10 | Because the health care facility may experience disruption in reimbursement during a pandemic, determine if the health care facility can amend its agreements with utilities to allow for delayed payment during a pandemic. See Contract Issues Third Party Reimbursement, Section H of the Legal module, and appropriate sections of Finance module. | | | | | |
| 11 | Identify or create contract language that requires utilities to continue performing, even if the health care facility cannot pay immediately during a pandemic. | | | | | |

H. CONTRACT ISSUES – UTILITIES CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|----|--|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 12 | Determine if the health care facility has any legal duty to protect the health of utility employees who come to the health care facility to make service calls during a pandemic. | | | | | |
| 13 | Determine if the health care facility has any duty to inform the utility employees of the potential risks associated with making service calls to the health care facility during a pandemic. | | | | | |
| 14 | Identify procedures and practices that could minimize the risks to the utility employees making service calls at the health care facility during a pandemic, including the procurement of medical and non-medical countermeasures. | | | | | |
| 15 | To the extent that a utility provider must come to the health care facility to perform a task, identify the impact on a utility's obligation to perform if the health care facility has been quarantined or is located within an area that has been quarantined. | | | | | |

CONTRACT ISSUES - UTILITIES

NEW JERSEY EXAMPLES

12. and 13. Health care facilities should review with legal counsel whether the health care facility or its medical staff have any duty to utility workers coming to the health care facility during a pandemic, or need to inform them about the potential risks associated with making service calls to the health care facility during a pandemic. Arguably, if there is a declared public health emergency, utilities and the public will be aware of the pandemic or other emergency, and will have received messages from government about the risks associated with the emergency.

Health care facilities should identify procedures and practices that could minimize the risks to utility workers making service calls to the facility during a pandemic, and consult with legal counsel to ensure that these procedures are documented.

H. CONTRACT ISSUES - THIRD PARTY REIMBURSEMENT STATUTORY AND REGULATORY ISSUES

During a pandemic, health care facilities must maintain a revenue stream to continue operating and providing health care services. Failure to maintain an adequate revenue stream may expose health care facilities to liability for, among other things, failure to meet contractual obligations to employees, vendors, contractors and other service providers. Federal and state statutes and regulations govern the manner in which third party payers are required to process and pay claims for health care services provided to members of private health plans, as well as those provided to individuals covered under state and federal health care programs. As the Finance module makes clear, continued payment from third party payers during an emergency is essential. Health care facilities must be familiar with these laws and regulations and must understand what, if anything, may change with regard to payment from third parties during an emergency. This section addresses the legal issues surrounding third party reimbursement.

In your plan, consider the following:

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|-------------------------|---|-----------|-------------|-------------|----------------------|-------------------|
| INITIAL PLANNING | | | | | | |
| 1 | Review state and federal statutes and regulations that govern health insurance plans, policies and payment systems. | | | | | |
| 2 | Identify state and federal statutes and regulations that specifically address third party reimbursement, including those that relate to publicly funded health insurance (Medicaid, SCHIP, and Medicare). | | | | | |

H. CONTRACT ISSUES - THIRD PARTY REIMBURSEMENT STATUTORY AND REGULATORY ISSUES CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|------------------------|--|-----------|-------------|-------------|----------------------|-------------------|
| 3 | Identify state and federal statutes and regulations that address reimbursement during a pandemic. | | | | | |
| PROMPT PAY LAWS | | | | | | |
| 4 | Review federal and state prompt payment statutes and regulations, 5 CFR § Part 1315 (2008). | | | | | |
| 5 | Identify provisions of the prompt payment regulations that address the timing of payment during an emergency, including a pandemic. | | | | | |
| 6 | Consider pursuing legislation to ensure prompt processing and payment of claims during a pandemic including periodic interim payments (PIP). | | | | | |

H. CONTRACT ISSUES - THIRD PARTY REIMBURSEMENT STATUTORY AND REGULATORY ISSUES CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|--------------------------|---|-----------|-------------|-------------|----------------------|-------------------|
| 7 | <p>Evaluate the methods by which a health care facility can expedite payments from payers during a pandemic for:</p> <ul style="list-style-type: none"> • Private payers • Federal health care programs • State health care programs <p>Medicare Part A allows for accelerated payments, whereas Medicare Part B permits intermediaries to advance payments. See Finance module.</p> | | | | | |
| CLAIMS SUBMISSION | | | | | | |
| 8 | <p>Review state and federal statutes and regulations related to billing and/or claims submission requirements for health care facilities.</p> | | | | | |
| 9 | <p>Identify any statutes or regulations regarding billing and claims submission with which it may be difficult to comply during a pandemic.</p> | | | | | |

H. CONTRACT ISSUES - THIRD PARTY REIMBURSEMENT STATUTORY AND REGULATORY ISSUES CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|----|---|-----------|-------------|-------------|----------------------|-------------------|
| 10 | Determine whether these statutes or regulations can be waived during a pandemic. | | | | | |
| 11 | Determine whether there are state statutes or regulations regarding waiver of certain requirements, including: claims submission and/or claims processing; eligibility; authorization; pre-certification; utilization review; coding; and medical record requirements during a declared state of emergency or pandemic. | | | | | |
| 12 | Identify the ramifications for failure to submit claims properly during a pandemic and to receive reimbursement. See Finance module. | | | | | |

H. CONTRACT ISSUES - THIRD PARTY REIMBURSEMENT STATUTORY AND REGULATORY ISSUES CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---------------------|--|-----------|-------------|-------------|----------------------|-------------------|
| STAFFORD ACT | | | | | | |
| 13 | Review the Stafford Act, 42 U.S.C. § 5121-5206 (2008), and determine whether a pandemic will be a "major disaster" or "emergency" as those terms are defined in the Act. | | | | | |
| 14 | Determine whether the health care facility is eligible for payment under the Stafford Act. Consider that compensation under the Act is only available for nonprofit entities, but for-profit entities may be able to enter into a relationship with a nonprofit entity which will entitle the for-profit entity to compensation. | | | | | |
| 15 | Be familiar with FEMA's Disaster Assistance Policy for Emergency Assistance for Human Influenza. See Appendix G. | | | | | |

H. CONTRACT ISSUES - THIRD PARTY REIMBURSEMENT STATUTORY AND REGULATORY ISSUES CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|-----|--|-----------|-------------|-------------|----------------------|-------------------|
| 16 | Determine the availability of payment for services provided by a health care facility in response to a pandemic. See Finance module A.18. | | | | | |
| 16a | Consider the distinction between definitive medical care, emergency medical care and sheltering. | | | | | |
| 16b | Consider the availability of reimbursement for the purchase of "medicine and other consumable supplies." | | | | | |
| 17 | To the extent the health care facility is part of a special needs shelter plan, determine whether reimbursement is available for these activities. | | | | | |

H. CONTRACT ISSUES - THIRD PARTY REIMBURSEMENT STATUTORY AND REGULATORY ISSUES CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|-----------------------------|---|-----------|-------------|-------------|----------------------|-------------------|
| SECTION 1135 WAIVERS | | | | | | |
| 18 | Understand the Secretary of the Department of Health and Human Service's ability to waive certain Medicare requirements under Section 1135 of the Social Security Act. These waivers may help providers who are unable to meet the requirements of the Social Security Act to be reimbursed for items and services furnished in good faith during a pandemic. | | | | | |
| 19 | Determine how the health care facility will obtain a copy of a Section 1135 waiver if one is issued. | | | | | |
| 20 | Determine who will carefully review the Section 1135 waiver to understand its implications. | | | | | |
| 21 | Develop processes for implementing any changes allowed by a Section 1135 waiver. | | | | | |

H. CONTRACT ISSUES - THIRD PARTY REIMBURSEMENT STATUTORY AND REGULATORY ISSUES CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|----|---|-----------|-------------|-------------|----------------------|-------------------|
| 22 | If a Section 1135 waiver is not issued and the health care facility is unable to comply with applicable Medicare regulations, determine whether it will still be eligible for Medicare/Medicaid reimbursement. See Health Care Facility Licensure and Regulatory Issues, Section C of the Legal module. | | | | | |

CONTRACT ISSUES - THIRD PARTY REIMBURSEMENT STATUTORY AND REGULATORY ISSUES

NEW JERSEY EXAMPLES

Initial Planning

1. The *New Jersey Influenza Pandemic Plan* (June 2008), Section VII.C. "Health Care Planning" includes information about the state's plans for addressing obstacles to health care planning, including health insurance payment issues (available at: http://www.state.nj.us/health/flu/panflu_plan.shtml).

N.J.S.A. § 26:2J-1 et seq. (2008) contains statutes regulating health maintenance organizations (HMOs).

2. There are various New Jersey statutes and regulations that address third party reimbursement, including:

- N.J.S.A. § 26:2j-1 et seq. (2008): Health Maintenance Organizations
- N.J.S.A. § 30:4D-1 et seq. (2008): Medical Assistance and Health Services Act
- N.J.S.A. § 30:4J-1 et seq. (2008): Family Care Health Coverage Act
- N.J.A.C. § 10:49 (2008): Medicaid Managed Care – New Jersey 2000 Services
- N.J.A.C. § 10:69 (2008): AFDC-Related Medicaid
- N.J.A.C. § 10:74 (2008): Managed Health Care Services for Medicaid Beneficiaries and NJ Kid Care Beneficiaries
- N.J.A.C. § 10:78 (2008): NJ Family Care
- N.J.A.C. § 11:24 (2008): Health Maintenance Organizations

Prompt Pay Laws

4. New Jersey's prompt payment law can be found in N.J.A.C. § 11:22-1.1 (2008). This regulation requires carriers and their agents to remit clean claims within 30 days after receipt of the claim where the claim is submitted by electronic means, or the time established for the Federal Medicare program by 42 U.S.C. § 1395 u(c)2(B) (2008), whichever is earlier; or, if the claim is not submitted electronically, within 40 calendar days after receipt. For claims denied or disputed because of missing information, the claims shall be paid within 30 or 40 calendar days of receipt of the missing information, pursuant to the electronic or non-electronic submission time frames set forth above.

5. The New Jersey Prompt Payment statutes and regulations do not address whether these time frames for prompt payment may be altered during a pandemic or other emergency. Consider, too, that the fiscal intermediaries and programs that administer health insurance plans will be experiencing severe staff shortages during a pandemic and may have trouble complying with the applicable regulations.

Claims Submission

10 and 11. The New Jersey Emergency Health Powers Act directs the commissioner of Health and Senior Services to "confer with the Commissioner of Banking and Insurance to request that the Department of Banking and Insurance waive regulations requiring compliance by a health care provider or health care facility with a managed care plan's administrative protocols, including but not limited to, prior authorization and pre-certification" (N.J.S.A. § 26:13-9(b)(5) (2008)). As a result, during a public health emergency, it will be important for health care facilities to not only monitor the orders issued by the commissioner of NJDHSS, but also the orders issued by the Commissioner of Banking and Insurance. Counsel should be familiar with the Commissioner of Banking and Insurance's ability to suspend such regulations and the process for such actions. Health care facilities may consider entering into discussions with the Commissioner of Banking and Insurance to determine whether his/her power to waive regulations is limited to those regulations specifically referenced in the Emergency Health Powers Act, or goes beyond these regulations.

H. CONTRACT ISSUES - THIRD PARTY REIMBURSEMENT PAYER CONTRACT ISSUES

Health care facilities generally have detailed agreements with various third party payers that govern the manner in which facilities must submit claims for reimbursement; whether services provided are covered services, pre-certification, referral requirements; and various other matters that ultimately determine whether the health care facility is reimbursed for the care provided. Both parties to such an agreement may find it difficult to comply with the terms of the agreement during an emergency. Health care facilities must determine what provisions of the agreement may be difficult to meet, as well as those a payer may have trouble meeting, during an emergency. This section addresses the legal issues related to payer contracts.

In your plan, consider the following:

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|------------------------------------|--|-----------|-------------|-------------|----------------------|-------------------|
| THIRD PARTY PAYOR CONTRACTS | | | | | | |
| 1 | Identify the appropriate contact person responsible for managed care contracts and related health insurance matters at the State Bureau of Insurance, State Department of Health and State Department of Medical Assistance. | | | | | |
| 2 | Review all third party payer contracts with a focus on provisions that require continued payment during pandemic. | | | | | |
| 3 | Evaluate how provisions in third party payer contracts that address the manner in which claims must be submitted to ensure proper reimbursement are likely to be affected during a pandemic. | | | | | |

H. CONTRACT ISSUES - THIRD PARTY REIMBURSEMENT PAYER CONTRACT ISSUES
CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|--|-----------|-------------|-------------|----------------------|-------------------|
| 4 | <p>Engage in discussions with third party payers regarding amendments to contracts to address alternative payment and claims submission processes during a pandemic.</p> <ul style="list-style-type: none"> • Create minimum data sets to be used during emergencies. See Finance module. • Consider allowing for reimbursement for services delivered during a pandemic by providers who do not ordinarily provide such services. • Consider eliminating the need for authorization, pre-certification and utilization management during a declared emergency or pandemic. See Finance module. | | | | | |

H. CONTRACT ISSUES - THIRD PARTY REIMBURSEMENT PAYER CONTRACT ISSUES
CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|--|-----------|-------------|-------------|----------------------|-------------------|
| INSURING AGAINST RISKS PRESENTED BY A PANDEMIC | | | | | | |
| 5 | Determine the types of risks against which the health care facility should insure related to a pandemic. Consider lost profits related to governmental closure or quarantine orders; commandeering of the facility; lack of reimbursement for services provided; and contamination with an infectious disease. | | | | | |
| 6 | Identify and review any insurance policies that the health care facility has related to the risks identified in Item 5. Consider business interruption insurance, civil authority coverage, ingress/egress coverage, contingent business interruption insurance and accounts receivable coverage. | | | | | |
| 7 | Determine whether a pandemic is a "covered peril" under the identified policies. | | | | | |

H. CONTRACT ISSUES - THIRD PARTY REIMBURSEMENT PAYER CONTRACT ISSUES
CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|----|---|-----------|-------------|-------------|----------------------|-------------------|
| 8 | Evaluate whether the identified insurance policies are only triggered by physical damage to the health care facility. If so, determine whether contamination by an infectious agent (e.g., pandemic influenza) is sufficient physical damage. | | | | | |
| 9 | Determine whether the identified insurance policies allow for payment to the health care facility in circumstances other than a complete cessation of operations. | | | | | |
| 10 | Determine whether the health care facility's civil authority coverage can be triggered by a preventative civil authority order. | | | | | |

H. CONTRACT ISSUES - BOND & DEBT CONTRACTS

Most health care facilities have a variety of bond and debt agreements in place to finance capital projects. These arrangements contain detailed covenants that mandate the health care facility meet specific financial performance metrics. It is very likely that it may be difficult to meet these covenants during an emergency. Counsel for health care facilities should be aware of all existing bond and debt covenants and the circumstances or events that constitute default. Health care facilities must plan for ways in which they can continue to meet obligations under these contracts during an emergency.

In your plan, consider the following:

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|--|-----------|-------------|-------------|----------------------|-------------------|
| 1 | Identify what events constitute a default under the health care facility's existing bond and debt agreements. | | | | | |
| 2 | Identify if revenue disruption is an event of default under the health care facility's existing bond and debt contracts. | | | | | |
| 3 | If revenue disruption is an event of default, determine what level of revenue disruption triggers default. Even if revenue disruption is not a specified event of default, evaluate all financial metrics in the covenants in light of the expected reduction in collections. | | | | | |

H. CONTRACT ISSUES - **BOND & DEBT CONTRACTS CONTINUED**

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|---|-----------|-------------|-------------|----------------------|-------------------|
| 4 | Identify any provisions of the bond and debt contracts that allow for waiver of certain health care facility obligations during a pandemic. Consider waivers related to: <ul style="list-style-type: none"> • Payment of principle • Forbearance of interest • Adjustment of the interest rate | | | | | |
| 5 | Amend bond and debt contracts to the extent possible to make them more favorable to the health care facility during a pandemic, understanding that this may not be possible. | | | | | |

I. ALTERNATE CARE SITES - INITIAL PLANNING

During a pandemic, it may be necessary for health care facilities to use alternate care sites (ACS) to provide care and add patient capacity. ACS are sites that are not currently part of the health care delivery system, such as stadiums, schools, gymnasiums and community centers that can be used to provide care for patients during a pandemic or other emergency when the health care system is operating at surge capacity. Health care facilities should become familiar with the local, state and federal laws and regulations that govern the selection and use of ACS as well as the contractual, liability and reimbursement issues related to operating ACS. Selection of appropriate ACS is an essential part of emergency planning. These sites should be accessible, secure, safe and clean, and should be able to accommodate the needs of staff, patients, family members and visitors, including those with special needs. Some states leave the selection of ACS to local health departments, while others may permit health care facilities to designate their own sites. Health care facilities must become familiar with how ACS will be selected and how these sites are used during an emergency.

In your plan, consider the following:

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---------------------------------|--|-----------|-------------|-------------|----------------------|-------------------|
| STATUTES AND REGULATIONS | | | | | | |
| 1 | Review the emergency services law and other state statutes and regulations for the definition of alternate care sites (ACS). | | | | | |
| 2 | Review the emergency services act and other state statutes and regulations regarding the process for selection, designation and deployment of ACS. | | | | | |

I. ALTERNATE CARE SITES - INITIAL PLANNING CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|----------------------------|--|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 3 | Identify any limitations on how ACS may be used. Determine whether there are any regulations, ordinances, etc., that limit the ways in which certain spaces (e.g., public schools or a government-owned location) may be used. | | | | | |
| 4 | Determine if there are any regulations or statutes that will need to be suspended or waived to deal with mass fatality management issues at the ACS. | | | | | |
| OVERSIGHT AUTHORITY | | | | | | |
| 5 | Identify the individuals or agencies (e.g., the state health department) responsible for selecting government-contracted ACS. | | | | | |
| 6 | Determine who may operate an ACS—local health departments, private entities or both. | | | | | |
| 7 | Determine whether health care facilities may select and operate their own ACS, or must use those sites selected by a government entity. | | | | | |

I. ALTERNATE CARE SITES - INITIAL PLANNING CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|-------------------|--|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 8 | Determine who is responsible for opening an ACS once a pandemic has been declared. | | | | | |
| 9 | Identify who is responsible for closing an ACS at the end of the pandemic. | | | | | |
| OPERATIONS | | | | | | |
| 10 | Identify what, if any, incident command structure (ICS) must be used at the ACS. | | | | | |
| 11 | Identify any government selected ACS in the area. | | | | | |
| 12 | If health care facilities may select their own ACS, identify and create a list of locations in the health care facility's area that may be used as ACS. Consider the legal issues related to using each site. See Alternate Care Sites Contract Issues Related to Management and Oversight, Section G of the Legal module. | | | | | |
| 13 | For each potential ACS, identify the individual(s) with the authority to permit use of the location as an ACS. | | | | | |

I. ALTERNATE CARE SITES - INITIAL PLANNING CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|----|--|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 14 | Determine whether potential ACSs in the region served by the health care facility have already entered into contracts or MOUs to serve as ACS. | | | | | |
| 15 | Consider and assess access, safety, security, technology and privacy issues when choosing an ACS. | | | | | |

ALTERNATE CARE SITES - INITIAL PLANNING

NEW JERSEY EXAMPLES

1. The *New Jersey Influenza Pandemic Plan* (June 2008), Section VII.C. "Health Care Planning" includes information about the state's plans for using alternate care sites (available at: http://www.state.nj.us/health/flu/panflu_plan.shtml).

11. The New Jersey Department of Health and Senior Services issued a *Pandemic Preparedness Planning Template for Federally Qualified Health Care Centers (FQHC)* in July 2007. This document suggests that FQHCs should be prepared to serve as alternate care sites during a health care surge related to a pandemic or other emergency (available at: www.state.nj.us/health/flu/documents/fqhc.pdf).

I. ALTERNATE CARE SITES - CONTRACT ISSUES RELATED TO MANAGEMENT AND OVERSIGHT

If the state allows private entities to select and operate alternate care sites (ACS), the health care facility may decide to set up and operate its own ACS. In doing so, health care facilities will need to enter into contracts with the owner of the ACS; vendors to provide supplies and equipment; security personnel; staff; vendors to store and deliver stockpiles of supplies and equipment; and other vendors to support the opening and operation of the site. Health care facilities must carefully consider the provisions of these contracts to ensure that the sites chosen can be efficiently opened and operated, and that the health care facility and its staff are protected from liability to the maximum extent possible.

In your plan, consider the following:

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|---|-----------|-------------|-------------|----------------------|-------------------|
| 1 | Identify and review health care facility policies and procedures for entering into contracts or MOUs with owners of potential ACS sites. Consider developing such policies and procedures if they do not currently exist. | | | | | |
| 2 | For each potential ACS site, identify those individuals with the authority to enter into contracts to make the site available to the health care facility during a pandemic. | | | | | |
| 3 | Identify key contractual elements the health care facility should consider in its contracts with ACS sites. | | | | | |

I. ALTERNATE CARE SITES - CONTRACT ISSUES RELATED TO MANAGEMENT AND OVERSIGHT CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|---|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 4 | Identify the entity or individuals responsible for the operation, management and oversight of each ACS. | | | | | |
| 5 | Determine whether and how the health care facility will compensate each ACS site for using its facilities. | | | | | |
| 6 | Determine whether there are local, state or federal funds available to health care facilities to compensate the owners of an ACS site during a pandemic. | | | | | |
| 7 | Carefully review the contractual requirements for operating the ACS. Note any specific requirements for special needs populations. | | | | | |
| 8 | Create a list of the necessary services to be provided at each ACS. | | | | | |
| 9 | Determine the level of care to be provided at each ACS (e.g., triage, inpatient care, critical care, etc.). Consider the legal issues, including licensure, related to the level of care. See Staffing Issues, Section F of the Legal module. | | | | | |

I. ALTERNATE CARE SITES - CONTRACT ISSUES RELATED TO MANAGEMENT AND OVERSIGHT CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|----|--|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 10 | <p>Determine the parameters for an MOU with the ACS site owner. Ensure that any MOU created outlines the following:</p> <ul style="list-style-type: none"> • Define the scope of permitted use(s) • Timing of use • Duration of use • Allocation of risk • Compensation | | | | | |
| 11 | <p>Determine how medicines and medical supplies will be delivered to and maintained at the ACS. Consider:</p> <ul style="list-style-type: none"> • Vendor agreements • MOUs with other area/regional health care facilities and pharmacies | | | | | |

I. ALTERNATE CARE SITES - CONTRACT ISSUES RELATED TO MANAGEMENT AND OVERSIGHT CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|----|--|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 12 | <p>Identify vendors to supply staff and services including security, food preparation, housekeeping and laundry at the ACS. Consider:</p> <ul style="list-style-type: none"> • Vendor agreements • MOUs with other area/regional health care facilities • Agreements with local police and fire departments to provide off-duty personnel for security. | | | | | |
| 13 | <p>Determine how the ACS will be staffed. Consider contracting with staffing agencies or entering into MOUs with volunteer organizations to ensure adequate staffing to meet the needs of the ACS. Consider the legal issues related to staffing, including employment issues. See HR module and Staffing, Section F of the Legal module.</p> | | | | | |
| 14 | <p>Identify who is responsible for mass fatality management at the ACS.</p> | | | | | |

I. ALTERNATE CARE SITES - LIABILITY ISSUES

In most cases, alternate care sites (ACS) are not designed to operate as health care facilities during non-emergency times; therefore, they are not capable of operating at the level and in the same manner as traditional health care facilities. For example, ACSs are not built to hospital specifications and do not have the built-in electrical, gases or systems that are available in traditional health care facilities. Numerous liability issues must be considered in selecting, operating and staffing an ACS. These issues are highlighted below and should be carefully evaluated by any health care facility deciding to operate an ACS or provide staff to an ACS.

In your plan, consider the following:

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|--|-----------|-------------|-------------|----------------------|-------------------|
| 1 | Identify potential liabilities for a health care facility that operates an ACS. Consider premises liability, malpractice liability and contractual liability with the owner of the ACS site and various vendors. | | | | | |
| 2 | Determine whether the provider or the site operator is responsible for obtaining premises liability insurance. | | | | | |
| 3 | Identify and review any liability protections available to health care facilities operating an ACS during a pandemic under state law. | | | | | |

I. ALTERNATE CARE SITES - LIABILITY ISSUES CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|--|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 4 | Identify potential liabilities for individual providers who provide care at an ACS. See HR module and Staffing Issues, Altered Standards of Care and Volunteers, Sections F, G and J of the Legal module. | | | | | |
| 5 | Determine whether the state has liability protections for paid health care providers who provide care at an ACS. | | | | | |
| 6 | Determine whether the state has liability protections for volunteer health care providers who provide care at an ACS. Evaluate if any distinction is made if volunteers are assigned by the health care facility or by the government. | | | | | |
| 7 | Consider that care provided at ACS may be provided at a different standard of care. See Altered Standards of Care, Section G of the Legal module. | | | | | |
| 8 | Review health care facility liability insurance policies to determine whether they address/cover care at an ACS, or can be modified to cover it. | | | | | |

I. ALTERNATE CARE SITES - LIABILITY ISSUES CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|----|--|-----------|-------------|-------------|----------------------|-------------------|
| 9 | Determine whether individual health care providers' liability insurance covers care provided at an ACS. | | | | | |
| 10 | Consider amending these policies or entering into special insurance policies to cover care provided by health care facility employees at an ACS during a pandemic. | | | | | |
| 11 | Determine whether the state has liability protections for the operators of ACS. If so, identify the requirements for eligibility. | | | | | |

I. ALTERNATE CARE SITES - LIABILITY ISSUES CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|----|---|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 12 | <p>Determine whether the intended clinical and operational services to be provided at each ACS can be provided safely and in compliance with relevant regulations and statutes (unless these have been waived or suspended by the state or federal government). Consider:</p> <ul style="list-style-type: none"> • Laboratory testing • Pharmaceutical services • Dietary • Operating rooms (OR) • Imaging capabilities • Intensive care units (ICU) • Outpatient clinics • Triage • Emergency room services <p>See Health Care Facility Licensure and Regulatory Issues, Section C of the Legal module.</p> | | | | | |

I. ALTERNATE CARE SITES - LIABILITY ISSUES CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|----|--|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 13 | Identify any other operational issues that may carry liability, including but not limited to: <ul style="list-style-type: none"> • Hazardous waste management • Infectious waste management | | | | | |
| 14 | Identify if there are any qualified immunities available for contracted staffing services provided at an ACS. See HR module. | | | | | |
| 15 | Identify any potential workers' compensation issues associated with using an ACS, including whether workers' compensation laws in the state cover employees working at ACS. See HR module. | | | | | |
| 16 | Identify and obtain any permits or certifications required to operate an ACS. Determine if waivers are available for these sites. See Health Care Facility Licensure and Regulatory Issues, Section C of the Legal module. | | | | | |

I. ALTERNATE CARE SITES - REIMBURSEMENT

Alternate care sites (ACS) will generally not be licensed health care facilities; therefore, the care provided at these sites is not necessarily eligible for reimbursement. These sites will no doubt be costly to operate. Health care facilities that operate ACS must investigate and be familiar with the available methods for and legal issues related to reimbursement for care delivered at an ACS.

In your plan, consider the following:

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|---|-----------|-------------|-------------|----------------------|-------------------|
| 1 | Identify any state, federal or third party payer reimbursement issues relevant to ACS. See Finance module and Contract Issues Third Party Reimbursement, Section H of the Legal module. | | | | | |
| 2 | Determine how the health care facility may be reimbursed, if at all, for care delivered at an ACS. Evaluate the legal ramifications if the health care facility is unable to obtain reimbursement for care delivered at an ACS. See Finance module and Health Care Facility Licensure and Regulatory Issues, Section C of the Legal module. | | | | | |
| 3 | Determine whether third party payer contracts can be amended to include reimbursement for care provided at an ACS. | | | | | |

I. ALTERNATE CARE SITES – REIMBURSEMENT CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|--|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 4 | Determine who is responsible for identifying funding sources for an ACS (e.g., state and/or local government, the health care facility, etc.). | | | | | |
| 5 | Review and evaluate Section 1135 of the Social Security Act to determine whether an 1135 waiver may be applied to care delivered at an ACS. See Finance module and Contract Issues Third Party Reimbursement, Section H of the Legal module. | | | | | |

J. VOLUNTEERS - INITIAL PLANNING

In emergencies, medical and non-medical volunteers can be an important part of a health care facility's emergency response effort. Volunteers may come from the community in which the health care facility is located, from neighboring localities or from other states. Volunteers can be used to supplement existing medical staff at a health care facility or alternate care site, cover gaps in services for health care facility staff unable to serve during an emergency or act as relief staff to the health care facilities primary medical staff. In a pandemic, it is unclear the extent to which volunteers will be available to serve. Health care facilities should evaluate how volunteers will be identified, how volunteers will be used during a pandemic and what liability protections are needed for the health care facility and the volunteers. Health care facilities should also develop contingency plans, should volunteers be unavailable or not immediately available.

In your plan, consider the following:

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|--|-----------|-------------|-------------|----------------------|-------------------|
| 1 | Determine if volunteers will be used to supplement health care facility staff in a pandemic. | | | | | |
| 2 | Determine if the health care facility needs liability insurance for volunteers during a pandemic, and whether the facility already has this coverage or needs to purchase additional coverage. | | | | | |

J. VOLUNTEERS - INITIAL PLANNING CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|---|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 3 | <p>Identify the sources for medical and non-medical volunteers available to the health care facility during a pandemic. Sources of volunteers include:</p> <ul style="list-style-type: none"> • State emergency health care volunteer registries like the Emergency System for the Advanced Registration of Volunteer Health Professionals (ESAR-VHP) or similar state systems • Local Medical Reserve Corps (MRC) units • State or local Red Cross units • Established local volunteer groups • Medical societies or associations | | | | | |
| 4 | <p>Review the state's law adopting the Emergency Management Assistance Compact (EMAC) to understand how out-of-state volunteers may be used during a pandemic, or how health care facility's employees may be deployed by the state to other states.</p> | | | | | |

J. VOLUNTEERS - INITIAL PLANNING CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|--|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 5 | Decide in advance if the health care facility will accept walk-up medical and non-medical volunteers. If walk-up volunteers are accepted, institute a system for verifying credentials, privileges and background information. See Staffing Issues, Section F of the Legal module. | | | | | |
| 6 | Identify if volunteers have had background checks and determine who is responsible for conducting the background checks – the health care facility or the organization/agency sending the volunteers. Consider the status of the volunteer's professional licensure or certification, privileges and whether the volunteer has ever been subject to civil or criminal penalties. | | | | | |
| 7 | Develop a plan for instituting security measures (e.g., badges, etc.) to identify volunteers authorized to be in general working vs. restricted areas within the health care facility. Identify security measures to protect volunteers while at the health care facility. | | | | | |

J. VOLUNTEERS - INITIAL PLANNING CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|----|--|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 8 | Identify who is responsible for training volunteers, and determine the amount and level of training provided. | | | | | |
| 9 | Determine if volunteers will be offered vaccines/antivirals, personal protective equipment or other protective measures during a pandemic. If so, determine who is responsible for providing these measures – the health care facility or the organization or agency sending the volunteers. See Staffing Issues, Section F of the Legal module. | | | | | |
| 10 | Identify if the health care facility will provide volunteers with lodging and other basic necessities (e.g., food, personal hygiene items, etc.), and identify any potential liability issues involved with providing these items. | | | | | |

VOLUNTEERS -INITIAL PLANNING

NEW JERSEY EXAMPLES

1. The *New Jersey Influenza Pandemic Plan* (June 2008), Section VII.C. “Health Care Planning” includes information about the state’s plans for using volunteers and providing training and exercises, including the use of Medical Reserve Corps volunteers (available at: http://www.state.nj.us/health/flu/panflu_plan.shtml).
2. Volunteers registered with the New Jersey Emergency Health Care Provider Registry authorized by N.J.S.A. § 26:13-6 (2008) that provide “health care services on a voluntary basis shall not be liable for any civil damages as a result of the person’s acts or omissions in providing medical care or treatment related to the public health emergency in good faith and in accordance with the provisions of [the Emergency Health Powers Act]” (N.J.S.A. § 26:13-6g (2008)).
3. New Jersey’s Emergency Health Care Provider Registry may include “health care workers, public health workers and support services personnel who voluntarily consent to provide health care, public health services and support logistics during a public health emergency” (N.J.S.A. § 26:13-6 (2008)).
4. New Jersey has adopted the Emergency Management Assistance Compact (NJEMAC) at N.J.S.A. § 38A:20-4 et seq. (2008).
5. The New Jersey Emergency Health Powers Act authorizes the commissioner of health to designate all or part of a health care facility or other location as an emergency health care center (N.J.S.A. § 26:13-6c (2008)). A volunteer registered with the New Jersey Emergency Health Care Provider Registry may volunteer to perform services at any emergency health care center (N.J.S.A. § 26:13-6e (2008)). Volunteers registered with the New Jersey registry may have an identification card to verify their status as pre-registered volunteers. See Note 7 below.
6. During a declared public health emergency, the commissioner of health may waive privileging requirements for volunteers on the registry. Hospitals are directed to “permit registered emergency health care workers to exercise privileges at the health care facility for the duration of the public health emergency” (N.J.S.A. § 26:13-6f (2008)).

7. The New Jersey commissioner of health may “issue identification cards to health care workers, public health workers and support services personnel” included in the state’s Emergency Health Care Provider Registry. The cards will identify the volunteer worker; indicate that they are a registered New Jersey volunteer; identify their professional licensure or certification; and, should it be known, the volunteer’s usual area of practice (N.J.S.A. § 26:13-6a (2008)).
8. The New Jersey commissioner of health may require volunteers in the state’s Emergency Health Care Provider Registry to receive training in “the provision of health care, public health services and support services in an emergency or crisis as a condition of registration” (N.J.S.A. § 26:13-6 (2008)).

J. VOLUNTEERS - GOOD SAMARITAN AND OTHER VOLUNTEER PROTECTIONS

Governments often provide liability protection and compensation for injuries to volunteers as an incentive to retain skilled health care volunteers in emergencies. The type of protections and injury compensation available varies with the law or other mechanisms through which a health care professional volunteers. Volunteer protections are available through “Good Samaritan” laws, state emergency volunteer laws and federal emergency volunteer laws. Health care facilities must understand the differences among the various legal mechanisms for volunteers so that facility staff volunteering elsewhere will receive appropriate liability protection and injury compensation; and to ensure that they understand the rights of the health care professionals volunteering at the health care facility during an emergency. Health care facilities should carefully evaluate how “volunteer” is defined under a volunteer protection law, and whether or not volunteers are permitted to receive pay from their employer while volunteering and/or retain eligibility for liability and compensation protections.

In your plan, consider the following:

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|----------------------------|--|-----------|-------------|-------------|----------------------|-------------------|
| GOOD SAMARITAN LAWS | | | | | | |
| 1 | Identify if the state has a Good Samaritan law. Determine who is covered under the Good Samaritan law, the types of acts permitted and the extent of liability protections available under it. | | | | | |
| 2 | Determine if the state Good Samaritan law applies to organizations, associations, corporations or any other type of entity other than an individual person. | | | | | |
| 3 | Identify if and how the state's Good Samaritan law will apply during a pandemic. | | | | | |

J. VOLUNTEERS - GOOD SAMARITAN AND OTHER VOLUNTEER PROTECTIONS
CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|--|---|-----------|-------------|-------------|----------------------|-------------------|
| 4 | Determine if Good Samaritan protections will apply to care provided in the health care facility by paid health care facility staff during a pandemic. | | | | | |
| 5 | Determine if Good Samaritan protections will apply to care provided in the health care facility by non-paid volunteers during a pandemic. | | | | | |
| STATE VOLUNTEER PROTECTION LAWS | | | | | | |
| 6 | Identify if the state has an additional law that provides volunteer immunity protections and determine the extent of protections available under it. | | | | | |
| 7 | Identify how "volunteer" is defined for the purposes of immunity under the state's volunteer protections law. | | | | | |
| 8 | Determine if the definition of "volunteer" includes or excludes paid health care facility staff. | | | | | |
| 9 | Identify if and how the state's volunteer immunity protections apply to care provided during a pandemic. | | | | | |

J. VOLUNTEERS - GOOD SAMARITAN AND OTHER VOLUNTEER PROTECTIONS
CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|--|---|-----------|-------------|-------------|----------------------|-------------------|
| FEDERAL VOLUNTEER PROTECTION LAWS | | | | | | |
| 10 | Review the Federal Volunteer Protection Act and assess its applicability to the health care facility in terms of providing volunteers with liability protections and injury compensation. | | | | | |
| 11 | Understand that the definition of "volunteer" is limited under the VPA and plan accordingly. | | | | | |
| 12 | Determine if the definition of "volunteer" includes or excludes paid health care facility staff. | | | | | |
| 13 | Determine if there are any other federal mechanisms for deploying volunteers (e.g., National Disaster Medical System) under which health care facility staff may deploy. | | | | | |
| 14 | Identify if and how federal volunteer immunity protections apply to care provided during a pandemic at the health care facility. | | | | | |

J. VOLUNTEERS - GOOD SAMARITAN AND OTHER VOLUNTEER PROTECTIONS
CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|----|--|-----------|-------------|-------------|----------------------|-------------------|
| 15 | Determine if the federal government can federalize state-controlled personnel (or resources) during a pandemic. See Emergency Laws, Section B of the Legal module. | | | | | |

VOLUNTEERS - GOOD SAMARITAN AND OTHER VOLUNTEER PROTECTIONS

NEW JERSEY EXAMPLES

Good Samaritan Laws and Other Immunities for Health Care Personnel

1. New Jersey has a Good Samaritan Act that provides complete or partial immunity for specified actors responding to certain events, but does not contain a blanket provision addressing health care professionals providing care in an emergency (N.J.S.A. § 2A:62A-2 et seq. (2008)).

The Good Samaritan Act does provide physicians, nurses or medical technicians who draw or obtain specimens in a medically accepted manner at the request of a law enforcement officer, or subsequently delivers to a law enforcement officer immunity from civil or criminal liability, so long as the person exercised the skill and care ordinarily required by others in the profession (N.J.S.A. § 2A:62A-10 (2008)).

There are also a number of sections of the New Jersey Code that provide immunity for those providing health and medical services in certain situations. For example, N.J.S.A. § 2A:62A-1.3 (2008) provides immunity from civil liability for certain health care professionals. The statute states, “[i]f an individual's actual health care facility duty, including on-call duty, does not require a response to a patient emergency situation, a health care professional who, in good faith, responds to a life-threatening emergency or responds to a request for emergency assistance in a life-threatening emergency within a hospital or other health care facility, is not liable for civil damages as a result of an act or omission in the rendering of emergency care.”

Additionally, New Jersey has a statute that provides civil immunity for emergency care that provides any “individual, including a person licensed to practice any method of treatment of human ailments, disease, pain, injury, deformity, mental or physical condition, or licensed to render services ancillary thereto, or any person who is a volunteer member of a duly incorporated first aid and emergency or volunteer ambulance or rescue squad association, who in good faith renders emergency care at the scene of an accident or emergency to the victim or victims thereof, or while transporting the victim or victims thereof to a hospital or other facility where treatment or care is to be rendered, shall not be liable for any civil damages as a result of any acts or omissions by such person in rendering the emergency care” (N.J.S.A. § 2A:62A-1 (2008)). There is an exception for operation of a motor vehicle or willful and wanton acts of omission or commission.

4. and 5. This provision relates to a specific accident or emergency scene and transport from a scene; it does not seem applicable to a pandemic influenza scenario or on-going public health emergency; however, care would be covered to the extent that the care rendered on the scene during a pandemic or public health emergency fit the statutory parameters outlined. Health care facility legal counsel should review how the New Jersey courts have interpreted the scope of the state's Good Samaritan Law and similar protections for health care providers (e.g., *Velezquez v. Jiminez*, 763 A. 2nd 753 (2000), in which a physician who responded to an emergency call inside a hospital was not entitled to immunity under the state's Good Samaritan Law).

State Volunteer Protection Laws

6. Protections for volunteer health care professionals during a public health emergency are included in the New Jersey Emergency Health Powers Act (N.J.S.A. § 26:13-1 et seq. (2008)). See Emergency Laws, Section B of the Legal module.

New Jersey's Charitable Immunity Act (N.J.S.A. § 2A:53A-7 (2008)) addresses liability for nonprofit corporations and associations organized for religious, charitable, educational or hospital purposes. Trustees, directors, officer, employees, agents, servants or volunteers of a nonprofit corporation, society or association that is organized exclusively for religious, charitable or educational purposes are not liable for damages to any person who is a beneficiary of the organization's work due to the negligence of the organization's covered personnel (N.J.S.A. § 2A:53A-7a(2008)).

A nonprofit corporation, society or association that is organized exclusively for hospital purposes, or its trustees, directors, officers, employees, agents, servants or volunteers, are not liable for damages arising from negligence to a person who is a beneficiary of the organization (N.J.S.A. § 2A:53A-7b (2008)). Agents, employees or servants, however, remain liable as individuals for any negligence (N.J.S.A. § 2A:53A-7b (2008)). Because volunteers are not included in the list of persons retaining individual liability, it is not clear if they retain their immunity. The immunity against damage suits against nonprofit hospital corporations, however, is subject to a \$250,000 threshold. Such nonprofit corporations are "liable to respond in damages to such beneficiary who shall suffer damage from the negligence of such corporation, society or association or of its agents or servants to an amount not exceeding \$250,000, together with interest and costs of suit, as the result of any one accident (N.J.S.A. § 2A:53A-8 (2008)). To the extent that damages with interest and costs of suit exceeds \$250,000, the nonprofit corporation, etc. is not liable.

Nonprofit corporations and associations organized for religious, charitable, educational or hospital purposes, and their trustees, directors, officers, employees, agents, servants or volunteers, are not granted immunity from willful, wanton or grossly negligent acts of omission or commission, including sexual assault; damage caused as a result of the negligent operation of a motor vehicle; or acts by an independent contractor (N.J.S.A. § 2A:53A-7c (2008)).

The Charitable Immunity Act also extends to persons serving without compensation other than for actual expenses as a trustee, director, officer or voluntary member of a blood bank, subject to exceptions for willful, wanton or grossly negligent acts or operation of a motor vehicle (N.J.S.A. § 2A:53A-7.2 (2008)).

8. and 9. The Charitable Immunity Act explicitly excludes health care providers who are compensated as employees, agents or servants for the organization: “Nothing in this subsection shall be deemed to grant immunity to any health care provider, in the practice of his/her profession, who is a compensated employee, agent or servant of any nonprofit corporation, society or association organized exclusively for religious, charitable or educational purposes” (N.J.S.A. § 2A:53A-7(a) (2008)). It is not clear how the statute would apply to volunteer health care providers who are compensated by their employers, but not the organization covered by the Charitable Immunity Act. The act is also silent as to how “compensation” is defined and whether it would include items such as travel expenses, food, lodging, etc. Nothing in the act addresses the provision of care during emergencies. Hospitals providing volunteers to entities covered by the Charitable Immunity Act should evaluate how their staff would be covered, if at all, under the act.

Federal Volunteer Protection Laws

10. The Federal Volunteer Protection Act (VPA) (42 U.S.C.S § 14501-14505 (2008)) provides immunity to volunteers who are: acting within the scope of his/her responsibility; properly licensed, certified or authorized to engage in the activity or practice (if such licensure is required by the state in which the damage occurred); and those activities within the scope of the volunteer's responsibility. The harm cannot be caused by willful or criminal misconduct; gross negligence; reckless misconduct; a "conscious, flagrant indifference to the rights or safety of the individual harmed by the volunteer;" or by the operation of a motor vehicle, aircraft, or other vehicle for which an operator's license or insurance is required by the state (42 U.S.C.S § 14503 (2008)). The VPA does not provide immunity for the organization using or deploying the volunteers; it only covers the volunteers. Organizations and other entities may be eligible for liability protections under other federal and state laws.

The VPA explicitly preempts state laws to the extent they are inconsistent with the VPA; however, states are permitted to provide additional liability protections for volunteers performing services for a nonprofit organization or governmental entity (42 U.S.C. § 14502(a) (2008)). States may affirmatively opt out of the protections offered in the VPA, but must pass legislation in order to do so (42 U.S.C. § 14502ba (2008)). New Jersey has not opted out of the VPA.

11. The VPA narrowly defines volunteers eligible for coverage under the act. The VPA specifically protects volunteers (including officers, directors, trustees, and direct service volunteers) who perform services for a nonprofit organization or a governmental entity, and do not receive (1) compensation other than reasonable reimbursement or allowance for expenses actually incurred; or (2) anything of value in lieu of compensation in excess of \$500 per year (42 U.S.C.S § 14505(6) (2008)).

12. As noted above, the VPA has a narrow definition of volunteers, particularly as it relates to the amount of compensation volunteers are entitled to receive and still be considered volunteers. Hospital staff that volunteer with an organization covered by the VPA may not be compensated by the organization beyond the expenses and limited compensation outlined in Item 11 above.

13. There are several other mechanisms through which volunteers may be deployed by the federal government. The U.S. Department of Health and Human Services (DHHS) is empowered under ESF-8 to the National Response Plan to deploy volunteer health care providers to an emergency. DHHS has used two mechanisms to deploy volunteers pursuant to ESF-8. It has used the National Disaster Medical System (NDMS) to provide “intermittent disaster response personnel” (42 U.S.C. § 300hh-11 (2008)). Volunteers deployed under NDMS are entitled to federal legal protections, including liability immunity; workers compensation coverage; and re-employment protections. Additionally, during Hurricane Katrina, DHHS recruited volunteers through a web page on the department’s web site. DHHS considered volunteers deploying through this mechanism as non-paid temporary federal employees under Schedule A of the Excepted Service to the federal civil service rules (5 C.F.R. § 213.3102(i)(2) (2008)); these volunteers were entitled to liability protection, workers compensation and licensure waiver, but not re-employment guarantees. It is unknown if DHHS will deploy federal health volunteers through the Excepted Service mechanism again in future emergencies, particularly since DHHS has supported the creation of state emergency volunteer registries.

DHHS is also authorized to accept services from temporary volunteers with the Public Health Service (42 U.S.C. § 217(b) (2008)), but this is not limited to emergencies. Volunteers must enter into a formal agreement with the government to work without compensation to provide health care, or in the operation of a health care facility. The volunteer may only provide services in DHHS facilities, to beneficiaries of federal programs, or to individuals or groups authorized to receive care under DHHS programs (45 C.F.R. § 57.2 (2008)). The regulations do not explicitly require that volunteers are entitled to legal protections, but it permits them to be offered workers compensation, civil liability protection under the Federal Tort Claims Act and transportation expenses (45 C.F.R. § 57.5 (2008)).

Health care facilities should carefully evaluate all potential state and federal mechanisms for deploying health care volunteers during an emergency and determine which, if any, legal protections the individual volunteers and the hospital organization will be entitled. Close attention should be paid to the amount of compensation, if any, and the types of compensation a volunteer may receive without jeopardizing their volunteer status and the accompanying legal protections.

15. The federal government's authority to seize state resources and personnel in an emergency without the consent of the state is generally limited by the 10th Amendment to the U.S. Constitution. The Stafford Act authorizes the federal government to contract with state and local governments to conduct emergency assistance activities, but it does not permit the federal government to take state resources to fulfill its emergency assistance activities (42 U.S.C. § 5150 (2008)). The Stafford Act permits the federal government to accept and use the services of state and local government in conducting federal emergency assistance activities (42 U.S.C. § 5149(a) (2008)). The federal government and the states enter into MOUs and other agreements to allow for the use of and reimbursement for state resources used by the federal government in responding to an emergency.

The federal government is not a party to the Emergency Assistance Compact (EMAC), which is an agreement among the states and territories to provide mutual aid during an emergency; however, the federal government consented to the creation and content of EMAC (P.L. 104-321 (1996)). The federal government cannot use EMAC as a vehicle for using state resources in an emergency and it is not entitled to the protections under EMAC. The federal government will enter into separate MOUs or other agreements with states for using state resources during an emergency. EMAC does authorize the federal government to consult with the states about their emergency management responsibilities. States are required to submit copies of their state's adoption of EMAC to FEMA and other agencies as necessary.

J. VOLUNTEERS - EMAC AND OTHER MUTUAL AID AGREEMENTS

States use the Emergency Management Assistance Compact (EMAC) to request and send mutual aid between states during emergencies. In some states, private volunteers (e.g., persons who are not state or, in some instances, local government employees) may be eligible for deployment under EMAC if they are “deputized” as temporary state employees or agents of the state. If covered under EMAC, volunteers are eligible for liability and workers’ compensation protection. Some states may have formal intra-state mutual aid agreements or other authorizing statutes to permit localities within a state to exchange assistance in emergencies; volunteers under intra-state agreements may be similarly entitled to liability and workers’ compensation protections. States may also participate in other interstate emergency assistance compacts. Health care facilities sending volunteers under a compact should determine whether their staff will be eligible for liability protection and workers’ compensation and, if so, to what extent. Health care facilities receiving volunteers should be aware of the protections available to the volunteers they are receiving from the various compacts or agreements through which they have been deployed.

In your plan, consider the following:

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|---|-----------|-------------|-------------|----------------------|-------------------|
| 1 | Identify if the state plans on making a request for Emergency Management Assistance Compact (EMAC) assistance during a pandemic. | | | | | |
| 2 | Identify who is responsible under EMAC for credentialing and privileging volunteers and how will this be done. See Staffing Issues Section F of the Legal module. | | | | | |
| 3 | If the state brings in volunteers under EMAC, determine how and where the state intends to deploy the EMAC volunteers. | | | | | |

J. VOLUNTEERS - EMAC AND OTHER MUTUAL AID AGREEMENTS CONTINUED

| | ASSIGNMENT | COMPLETED | IN PROGRESS | NOT STARTED | DATE TO BE COMPLETED | LEAD STAFF MEMBER |
|---|--|------------------|--------------------|--------------------|-----------------------------|--------------------------|
| 4 | Determine if health care facility staff deployed out-of-state under EMAC will be deemed to be agents of the state or temporary state employees and provided with liability protection under EMAC. | | | | | |
| 5 | Identify the licensure reciprocity provisions of the state's EMAC agreement. | | | | | |
| 6 | Determine if using EMAC will make it easier for an out-of-state volunteer to provide care in the state receiving aid. | | | | | |
| 7 | Identify if there are other mutual aid agreements through which health care facility can place or receive volunteers. Other compacts can include: <ul style="list-style-type: none"> • Interstate regional compacts and MOUs • Local management assistance compacts and ordinances | | | | | |
| 8 | Identify the liability protections and injury compensation protections under each mutual aid agreement. | | | | | |
| 9 | Identify if the state will seek volunteers to deploy to other states under EMAC. | | | | | |

APPENDIX A

***CDC's INTERIM PRE-PANDEMIC PLANNING
GUIDANCE: COMMUNITY STRATEGY FOR
PANDEMIC INFLUENZA MITIGATION IN THE
UNITED STATES – EARLY, TARGETED,
LAYERED USE OF NON-PHARMACEUTICAL
INTERVENTIONS***



Interim Pre-pandemic Planning Guidance: Community Strategy for Pandemic Influenza Mitigation in the United States—

Early, Targeted, Layered Use of Nonpharmaceutical Interventions



**Interim Pre-Pandemic Planning Guidance:
Community Strategy for Pandemic Influenza Mitigation in the United States—
Early, Targeted, Layered Use of Nonpharmaceutical Interventions**



February 2007



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Executive Summary

Purpose

This document provides interim planning guidance for State, territorial, tribal, and local communities that focuses on several measures other than vaccination and drug treatment that might be useful during an influenza pandemic to reduce its harm. Communities, individuals and families, employers, schools, and other organizations will be asked to plan for the use of these interventions to help limit the spread of a pandemic, prevent disease and death, lessen the impact on the economy, and keep society functioning. This interim guidance introduces a Pandemic Severity Index to characterize the severity of a pandemic, provides planning recommendations for specific interventions that communities may use for a given level of pandemic severity, and suggests when these measures should be started and how long they should be used. The interim guidance will be updated when significant new information about the usefulness and feasibility of these approaches emerges.

Introduction

The Centers for Disease Control and Prevention, U.S. Department of Health and Human Services in collaboration with other Federal agencies and partners in the public health, education, business, healthcare, and private sectors, has developed this interim planning guidance on the use of nonpharmaceutical interventions to mitigate an influenza pandemic. These measures may serve as one component of a comprehensive community mitigation strategy that includes both pharmaceutical and nonpharmaceutical measures, and this interim guidance includes initial discussion of a potential strategy for combining the use of antiviral medications with these interventions. This guidance will be updated as new

information becomes available that better defines the epidemiology of influenza transmission, the effectiveness of control measures, and the social, ethical, economic, and logistical costs of mitigation strategies. Over time, exercises at the local, State, regional, and Federal level will help define the feasibility of these recommendations and ways to overcome barriers to successful implementation.

The goals of the Federal Government's response to pandemic influenza are to limit the spread of a pandemic; mitigate disease, suffering, and death; and sustain infrastructure and lessen the impact on the economy and the functioning of society. Without mitigating interventions, even a less severe pandemic would likely result in dramatic increases in the number of hospitalizations and deaths. In addition, an unmitigated severe pandemic would likely overwhelm our nation's critical healthcare services and impose significant stress on our nation's critical infrastructure. This guidance introduces, for the first time, a Pandemic Severity Index in which the case fatality ratio (the proportion of deaths among clinically ill persons) serves as the critical driver for categorizing the severity of a pandemic. The severity index is designed to enable better prediction of the impact of a pandemic and to provide local decision-makers with recommendations that are matched to the severity of future influenza pandemics.

It is highly unlikely that the most effective tool for mitigating a pandemic (i.e., a well-matched pandemic strain vaccine) will be available when a pandemic begins. This means that we must be prepared to face the first wave of the next pandemic without vaccine and potentially without sufficient quantities of influenza antiviral medications. In addition, it is

not known if influenza antiviral medications will be effective against a future pandemic strain. During a pandemic, decisions about how to protect the public before an effective vaccine is available need to be based on scientific data, ethical considerations, consideration of the public's perspective of the protective measures and the impact on society, and common sense. Evidence to determine the best strategies for protecting people during a pandemic is very limited. Retrospective data from past influenza pandemics and the conclusions drawn from those data need to be examined and analyzed within the context of modern society. Few of those conclusions may be completely generalizable; however, they can inform contemporary planning assumptions. When these assumptions are integrated into the current mathematical models, the limitations need to be recognized, as they were in a recent Institute of Medicine report (Institute of Medicine. Modeling Community Containment for Pandemic Influenza. A Letter Report. Washington, DC.: The National Academies Press; 2006).

The pandemic mitigation framework that is proposed is based upon an early, targeted, layered application of multiple partially effective nonpharmaceutical measures. It is recommended that the measures be initiated early before explosive growth of the epidemic and, in the case of severe pandemics, that they be maintained consistently during an epidemic wave in a community. The pandemic mitigation interventions described in this document include:

1. Isolation and treatment (as appropriate) with influenza antiviral medications of all persons with confirmed or probable pandemic influenza. Isolation may occur in the home or healthcare setting, depending on the severity of an individual's illness and /or the current capacity of the healthcare infrastructure.
2. Voluntary home quarantine of members of households with confirmed or probable influenza case(s) and consideration of combining this intervention with the prophylactic use of antiviral medications, providing sufficient quantities of effective medications exist and that a feasible means of distributing them is in place.

3. Dismissal of students from school (including public and private schools as well as colleges and universities) and school-based activities and closure of childcare programs, coupled with protecting children and teenagers through social distancing in the community to achieve reductions of out-of-school social contacts and community mixing.
4. Use of social distancing measures to reduce contact between adults in the community and workplace, including, for example, cancellation of large public gathering and alteration of workplace environments and schedules to decrease social density and preserve a healthy workplace to the greatest extent possible without disrupting essential services. Enable institution of workplace leave policies that align incentives and facilitate adherence with the nonpharmaceutical interventions (NPIs) outlined above.

All such community-based strategies should be used in combination with individual infection control measures, such as hand washing and cough etiquette.

Implementing these interventions in a timely and coordinated fashion will require advance planning. Communities must be prepared for the cascading second- and third-order consequences of the interventions, such as increased workplace absenteeism related to child-minding responsibilities if schools dismiss students and childcare programs close.

Decisions about what tools should be used during a pandemic should be based on the observed severity of the event, its impact on specific subpopulations, the expected benefit of the interventions, the feasibility of success in modern society, the direct and indirect costs, and the consequences on critical infrastructure, healthcare delivery, and society. The most controversial elements (e.g., prolonged dismissal of students from schools and closure of childcare programs) are not likely to be needed in less severe pandemics, but these steps may save lives during severe pandemics. Just as communities plan and prepare for mitigating the effect of severe natural disasters (e.g., hurricanes), they should plan and prepare for mitigating the effect of a severe pandemic.

Rationale for Proposed Nonpharmaceutical Interventions

The use of NPIs for mitigating a community-wide epidemic has three major goals: 1) delay the exponential growth in incident cases and shift the epidemic curve to the right in order to “buy time” for production and distribution of a well-matched pandemic strain vaccine, 2) decrease the epidemic peak, and 3) reduce the total number of incident cases, thus reducing community morbidity and mortality. Ultimately, reducing the number of persons infected is a primary goal of pandemic planning. NPIs may help reduce influenza transmission by reducing contact between sick and uninfected persons, thereby reducing the number of infected persons. Reducing the number of persons infected will, in turn, lessen the need for healthcare services and minimize the impact of a pandemic on the economy and society. The surge of need for medical care that would occur following a poorly mitigated severe pandemic can be addressed only partially by increasing capacity within hospitals and other care settings. Reshaping the demand for healthcare services by using NPIs is an important component of the overall mitigation strategy. In practice, this means reducing the burdens on the medical and public health infrastructure by decreasing demand for medical services at the peak of the epidemic and throughout the epidemic wave; by spreading the aggregate demand over a longer time; and, to the extent possible, by reducing net demand through reduction in patient numbers and case severity.

No intervention short of mass vaccination of the public will dramatically reduce transmission when used in isolation. Mathematical modeling of pandemic influenza scenarios in the United States, however, suggests that pandemic mitigation strategies utilizing multiple NPIs may decrease transmission substantially and that even greater reductions may be achieved when such measures are combined with the targeted use of antiviral medications for treatment and prophylaxis. Recent preliminary analyses of cities affected by the 1918 pandemic show a highly significant association between the early use of

multiple NPIs and reductions in peak and overall death rates. The rational targeting and layering of interventions, especially if these can be implemented before local epidemics have demonstrated exponential growth, provide hope that the effects of a severe pandemic can be mitigated. It will be critical to *target* those at the nexus of transmission and to *layer* multiple interventions together to reduce transmission to the greatest extent possible.

Pre-Pandemic Planning: the Pandemic Severity Index

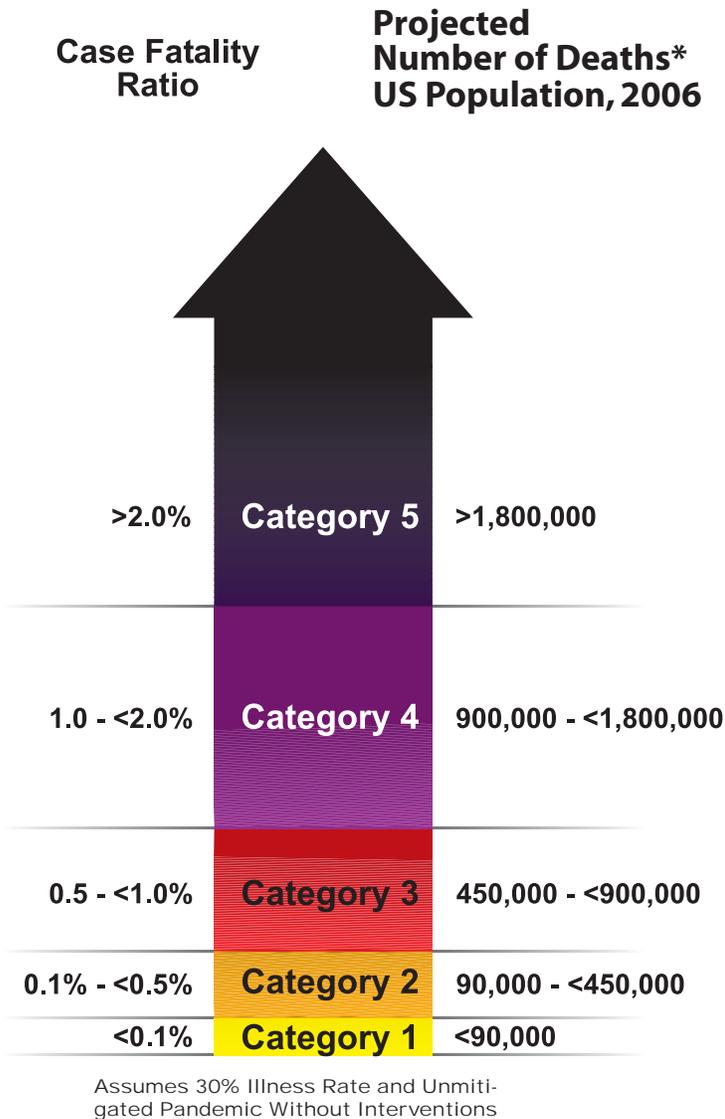
This guidance introduces, for the first time, a Pandemic Severity Index, which uses case fatality ratio as the critical driver for categorizing the severity of a pandemic (Figure 1, abstracted and reprinted here from figure 4 in the main text). The index is designed to enable estimation of the severity of a pandemic on a population level to allow better forecasting of the impact of a pandemic and to enable recommendations to be made on the use of mitigation interventions that are matched to the severity of future influenza pandemics.

Future pandemics will be assigned to one of five discrete categories of increasing severity (Category 1 to Category 5). The Pandemic Severity Index provides communities a tool for scenario-based contingency planning to guide local pre-pandemic preparedness efforts. Accordingly, communities facing the imminent arrival of pandemic disease will be able to use the pandemic severity assessment to define which pandemic mitigation interventions are indicated for implementation.

Use of Nonpharmaceutical Interventions by Severity Category

This interim guidance proposes a community mitigation strategy that matches recommendations on planning for use of selected NPIs to categories of severity of an influenza pandemic. These planning recommendations are made on the basis of an assessment of the possible benefit to be derived from

Figure 1. Pandemic Severity Index



implementation of these measures weighed against the cascading second- and third-order consequences that may arise from their use. Cascading second- and third-order consequences are chains of effects that may arise because of the intervention and may require additional planning and intervention to mitigate. The term generally refers to foreseeable unintended consequences of intervention. For example, dismissal of students from school may lead to the second-order effect of workplace absenteeism for child minding. Subsequent workplace absenteeism and loss of household income could be especially problematic for

individuals and families living at or near subsistence levels. Workplace absenteeism could also lead to disruption of the delivery of goods and services essential to the viability of the community.

For Category 4 or Category 5 pandemics, a planning recommendation is made for use of all listed NPIs (Table 1, abstracted and reprinted here from Table 2. in the main text). In addition, planning for dismissal of students from schools and school-based activities and closure of childcare programs, in combination with means to reduce out-of-school social contacts and community mixing for these children, should encompass up to 12 weeks of intervention in the most severe scenarios. This approach to pre-pandemic planning will provide a baseline of readiness for community response. Recommendations for use of these measures for pandemics of lesser severity may include a subset of these same interventions and potentially for shorter durations, as in the case of social distancing measures for children.

For Category 2 and Category 3 pandemics, planning for voluntary isolation of ill persons is recommended; however, other mitigation measures (e.g., voluntary quarantine of household members and social distancing measures for children and adults) should be implemented only if local decision-makers determine their use is warranted due to characteristics of the pandemic within their community. Pre-pandemic planning for the use of mitigation strategies within these two Pandemic Severity Index categories should be done with a focus on a duration of 4 weeks or less, distinct from the longer timeframe recommended for the more severe Category 4 and Category 5 pandemics. For Category 1 pandemics, voluntary isolation of ill persons is generally the only community-wide recommendation, although local communities may choose to tailor their response to Category 1-3 pandemics by applying NPIs on the basis of local epidemiologic parameters, risk assessment, availability of countermeasures, and consideration of local healthcare surge capacity. Thus, from a pre-pandemic planning perspective for Category 1, 2, and 3 pandemics, capabilities for both assessing local public health capacity and healthcare

surge, delivering countermeasures, and implementing these measures in full and in combination should be assessed.

Triggers for Initiating Use of Nonpharmaceutical Interventions

The timing of initiation of various NPIs will influence their effectiveness. Implementing these

measures prior to the pandemic may result in economic and social hardship without public health benefit and over time, may result in “intervention fatigue” and erosion of public adherence. Conversely, implementing these interventions after extensive spread of pandemic influenza illness in a community may limit the public health benefits of employing these measures. Identifying the optimal time for initiation of these interventions will be challenging because implementation needs to be early enough to preclude the initial steep upslope in case numbers and long enough to cover the peak of the anticipated epidemic curve while avoiding intervention fatigue.

This guidance suggests that the primary activation trigger for initiating interventions be the arrival and transmission of pandemic virus. This trigger is best defined by a laboratory-confirmed cluster of infection with a novel influenza

Table 1. Summary of the Community Mitigation Strategy by Pandemic Severity

| Interventions* by Setting | Pandemic Severity Index | | |
|---|---------------------------|-------------------------|---------------------------|
| | 1 | 2 and 3 | 4 and 5 |
| Home Voluntary isolation of ill at home (adults and children); combine with use of antiviral treatment as available and indicated | Recommend†§ | Recommend†§ | Recommend†§ |
| Voluntary quarantine of household members in homes with ill persons¶ (adults and children); consider combining with antiviral prophylaxis if effective, feasible, and quantities sufficient | Generally not recommended | Consider** | Recommend** |
| School Child social distancing -dismissal of students from schools and school based activities, and closure of child care programs -reduce out-of-school social contacts and community mixing | Generally not recommended | Consider: ≤4 weeks†† | Recommend: ≤12 weeks§§ |
| Workplace / Community Adult social distancing -decrease number of social contacts (e.g., encourage teleconferences, alternatives to face-to-face meetings) -increase distance between persons (e.g., reduce density in public transit, workplace) -modify postpone, or cancel selected public gatherings to promote social distance (e.g., postpone indoor stadium events, theatre performances) -modify work place schedules and practices (e.g., telework, staggered shifts) | Generally not recommended | Consider | Recommend |
| | Generally not recommended | Consider | Recommend |
| | Generally not recommended | Consider | Recommend |
| | Generally not recommended | Consider | Recommend |

Generally Not Recommended = Unless there is a compelling rationale for specific populations or jurisdictions, measures are generally not recommended for entire populations as the consequences may outweigh the benefits.

Consider = Important to consider these alternatives as part of a prudent planning strategy, considering characteristics of the pandemic, such as age-specific illness rate, geographic distribution, and the magnitude of adverse consequences.

These factors may vary globally, nationally, and locally.

Recommended = Generally recommended as an important component of the planning strategy.

*All these interventions should be used in combination with other infection control measures, including hand hygiene, cough etiquette, and personal protective equipment such as face masks. Additional information on infection control measures is available at www.pandemicflu.gov.

†This intervention may be combined with the treatment of sick individuals using antiviral medications and with vaccine campaigns, if supplies are available

§Many sick individuals who are not critically ill may be managed safely at home

¶The contribution made by contact with asymptotically infected individuals

to disease transmission is unclear. Household members in homes with ill persons may be at increased risk of contracting pandemic disease from an ill household member. These household members may have asymptomatic illness and may be able to shed influenza virus that promotes community disease transmission. Therefore, household members of homes with sick individuals would be advised to stay home.

**To facilitate compliance and decrease risk of household transmission, this intervention may be combined with provision of antiviral medications to household contacts, depending on drug availability, feasibility of distribution, and effectiveness; policy recommendations for antiviral prophylaxis are addressed in a separate guidance document.

††Consider short-term implementation of this measure—that is, less than 4 weeks.

§§Plan for prolonged implementation of this measure—that is, 1 to 3 months; actual duration may vary depending on transmission in the community as the pandemic wave is expected to last 6-8 weeks

virus and evidence of community transmission (i.e., epidemiologically linked cases from more than one household).

Defining the proper geospatial-temporal boundary for this cluster is complex and should recognize that our connectedness as communities goes beyond spatial proximity and includes ease, speed, and volume of travel between geopolitical jurisdictions (e.g., despite the physical distance, Hong Kong, London, and New York City may be more epidemiologically linked to each other than they are to their proximate rural provinces/areas). In order to balance connectedness and optimal timing, it is proposed that the geopolitical trigger be defined as the cluster of cases occurring within a U.S. State or proximate epidemiological region (e.g., a metropolitan area that spans more than one State's boundary). It is acknowledged that this definition of "region" is open to interpretation; however, it offers flexibility to State and local decision-makers while underscoring the need for regional coordination in pre-pandemic planning.

From a pre-pandemic planning perspective, the steps between recognition of a pandemic threat and the decision to activate a response are critical to successful implementation. Thus, a key component is the development of scenario-specific contingency plans for pandemic response that identify key personnel, critical resources, and processes. To emphasize the importance of this concept, the guidance section on triggers introduces the terminology of *Alert*, *Standby*, and *Activate*, which reflect key steps in escalation of response action. *Alert* includes notification of critical systems and personnel of their impending activation, *Standby* includes initiation of decision-making processes for imminent activation, including mobilization of resources and personnel, and *Activate* refers to implementation of the specified pandemic mitigation measures. Pre-pandemic planning for use of these interventions should be directed to lessening the transition time between *Alert*, *Standby*, and *Activate*. The speed of transmission may drive the amount of time decision-makers are allotted in each mode, as does the amount of time it takes to fully implement the intervention once a decision is made to *Activate*.

For the most severe pandemics (Categories 4 and 5), *Alert* is implemented during WHO Phase 5/U.S. Government Stage 2 (confirmed human outbreak overseas), and *Standby* is initiated during WHO Phase 6/Stage 3 (widespread human outbreaks in multiple locations overseas). *Standby* is maintained through Stage 4 (first human case in North America), with the exception of the State or region in which a cluster of laboratory-confirmed human pandemic influenza cases with evidence of community transmission is identified. The recommendation for that State or region is to *Activate* the appropriate NPIs when identification of a cluster with community transmission is made. Other States or regions *Activate* appropriate interventions when they identify laboratory-confirmed human pandemic influenza case clusters with evidence of community transmission in their jurisdictions.

For Category 1, 2, and 3 pandemics, *Alert* is declared during U.S. Government Stage 3, with step-wise progression by States and regions to *Standby* based on U.S. Government declaration of Stage 4 and the identification of the first human pandemic influenza case(s) in the United States. Progression to *Activate* by a given State or region occurs when that State or region identifies a cluster of laboratory-confirmed human pandemic influenza cases, with evidence of community transmission in their jurisdiction.

Duration of Implementation of Nonpharmaceutical Interventions

It is important to emphasize that as long as susceptible individuals are present in large numbers, Disease spread may continue. Immunity to infection with a pandemic strain can only occur after natural infection or immunization with an effective vaccine. Preliminary analysis of historical data from selected U.S. cities during the 1918 pandemic suggests that duration of implementation is significantly associated with overall mortality rates. Stopping or limiting the intensity of interventions while pandemic virus was still circulating within the community was temporally associated with increases in mortality due to pneumonia and influenza in many communities. It is recommended for planning purposes that

communities be prepared to maintain interventions for up to 12 weeks, especially in the case of Category 4 or Category 5 pandemics, where recrudescent epidemics may have significant impact. However, for less severe pandemics (Category 2 or 3), a shorter period of implementation may be adequate for achieving public health benefit. This planning recommendation acknowledges the uncertainty around duration of circulation of pandemic virus in a given community and the potential for recrudescent disease when use of NPIs is limited or stopped, unless population immunity is achieved.

Critical Issues for the Use of Nonpharmaceutical Interventions

A number of outstanding issues should be addressed to optimize the planning for use of these measures. These issues include the establishment of sensitive and timely surveillance, the planning and conducting of multi-level exercises to evaluate the feasibility of implementation, and the identification and establishment of appropriate monitoring and evaluation systems. Policy guidance in development regarding the use of antiviral medications for prophylaxis, community and workplace-specific use of personal protective equipment, and safe home management of ill persons must be prioritized as part of future components of the overall community mitigation strategy. In addition, generating appropriate risk communication content/materials and an effective means for delivery, soliciting active community support and involvement in strategic planning decisions, and assisting individuals and families in addressing their own preparedness needs are critical factors in achieving success.

Assessment of the Public on Feasibility of Implementation and Compliance

A Harvard School of Public Health public opinion poll on community mitigation interventions, conducted with a nationally representative sample of adults over the age of 18 years in the United States in September and October 2006, indicated that most respondents were willing to follow public

health recommendations for the use of NPIs, but it also uncovered financial and other concerns. More information on the poll is available at the “Pandemic Influenza and the Public: Survey Findings” available at http://www.keystone.org/Public_Policy/Pandemic_control.html.

The Public Engagement Project on Community Control Measures for Pandemic Influenza (see link at http://www.keystone.org/Public_Policy/Pandemic_control.html), carried out in October and November 2006, found that approximately two-thirds of both citizens and stakeholders supported all the nonpharmaceutical measures. Nearly half of the citizens and stakeholders supported implementation when pandemic influenza first strikes the United States, and approximately one-third of the public supported implementation when influenza first strikes in their State.

Although the findings from the poll and public engagement project reported high levels of willingness to follow pandemic mitigation recommendations, it is uncertain how the public might react when a pandemic occurs. These results need to be interpreted with caution in advance of a severe pandemic that could cause prolonged disruption of daily life and widespread illness in a community. Issues such as the ability to stay home if ill, job security, and income protection were repeatedly cited as factors critical to ensuring compliance with these NPI measures.

Planning to Minimize Consequences of Community Mitigation Strategy

It is recognized that implementing certain NPIs will have an impact on the daily activities and lives of individuals and society. For example, some individuals will need to stay home to mind children or because of exposure to ill family members, and for some children, there will be an interruption in their education or their access to school meal programs. These impacts will arise in addition to the direct impacts of the pandemic

itself. Communities should undertake appropriate planning to address both the consequences of these interventions and direct effects of the pandemic. In addition, communities should pre-identify those for whom these measures may be most difficult to implement, such as vulnerable populations and persons at risk (e.g., people who live alone or are poor/working poor, elderly [particularly those who are homebound], homeless, recent immigrants, disabled, institutionalized, or incarcerated). To facilitate preparedness and to reduce untoward consequences from these interventions, Pandemic Influenza Community Mitigation Interim Planning Guides have been included (see Appendices 4-9) to provide broad planning guidance tailored for businesses and other employers, childcare programs, elementary and secondary schools, colleges and universities, faith-based and community organizations, and individuals and families. It is also critical for communities to begin planning their risk communication strategies. This includes public engagement and messages to help individuals, families, employers, and many other stakeholders to prepare.

The U.S. Government recognizes the significant challenges and social costs that would be imposed by the coordinated application of the measures described above. It is important to bear in mind, however, that if the experience of the 1918 pandemic is relevant, social distancing and other NPI strategies would, in all likelihood, be implemented in most communities at some point during a pandemic. The potential exists for such interventions to be implemented in an uncoordinated, untimely, and inconsistent manner that would impose economic and social costs similar to those imposed by strategically implemented interventions but with dramatically reduced effectiveness. The development of clear interim pre-pandemic guidance for planning that outlines a coordinated strategy, based upon the best scientific evidence available, offers communities the best chance to secure the benefits that such strategies may provide. As States and local communities exercise the potential tools for responding to a pandemic, more will be learned about the practical realities of their implementation. Interim recommendations will be updated accordingly.

Testing and Exercising Community Mitigation Interventions

Since few communities have experienced disasters on the scale of a severe pandemic, drills and exercises are critical in testing the efficacy of plans. A severe pandemic would challenge all facets of governmental and community functions. Advance planning is necessary to ensure a coordinated communications strategy and the continuity of essential services. Realistic exercises considering the effect of these proposed interventions and the cascading second- and third-order consequences will identify planning and resource shortfalls.

Research Needs

It is recognized that additional research is needed to validate the proposed interventions, assess their effectiveness, and identify adverse consequences. This research will be conducted as soon as practicable and will be used in providing updated guidance as required. A proposed research agenda is outlined within this document.

Conclusions

Planning and preparedness for implementing mitigation strategies during a pandemic are complex tasks requiring participation by all levels of government and all segments of society. Community-level intervention strategies will call for specific actions by individuals, families, employers, schools, and other organizations. Building a foundation of community and individual and family preparedness and developing and delivering effective risk communication for the public in advance of a pandemic are critical. If embraced earnestly, these efforts will result in enhanced ability to respond not only to pandemic influenza but also to multiple other hazards and threats. While the challenge is formidable, the consequences of facing a severe pandemic unprepared will be intolerable. This interim pre-pandemic planning guidance is put forth as a step in our commitment to address the challenge of mitigating a pandemic by building and enhancing community resiliency.

Introduction

A severe pandemic in a fully susceptible population, such as the 1918 pandemic or one of even greater severity, with limited quantities of antiviral medications and pre-pandemic vaccine represents a worst-case scenario for pandemic planning and preparedness.¹ However, because pandemics are unpredictable in terms of timing, onset, and severity, communities must plan and prepare for the spectrum of pandemic severity that could occur. The purpose of this document is to provide interim planning guidance for what are believed currently to be the most effective combinations of pharmaceutical and nonpharmaceutical interventions (NPIs) for mitigating the impact of an influenza pandemic across a wide range of severity scenarios.

The community strategy for pandemic influenza mitigation supports the goals of the Federal Government's response to pandemic influenza to limit the spread of a pandemic; mitigate disease, suffering, and death; and sustain infrastructure and lessen the impact to the economy and the functioning of society.² In a pandemic, the overarching public health imperative must be to reduce morbidity and mortality. From a public health perspective, if we fail to protect human health we are likely to fail in our goals of preserving societal function and mitigating the social and economic consequences of a severe pandemic.³⁻⁸

A severe pandemic could overwhelm acute care services in the United States and challenge our nation's healthcare system.⁹⁻¹¹ To preserve as many lives as possible, it is essential to keep the healthcare system functioning and to deliver the best care possible.¹² The projected peak demand for healthcare services, including intensive care unit (ICU) admissions and the number of individuals requiring mechanical ventilation, would vastly exceed current

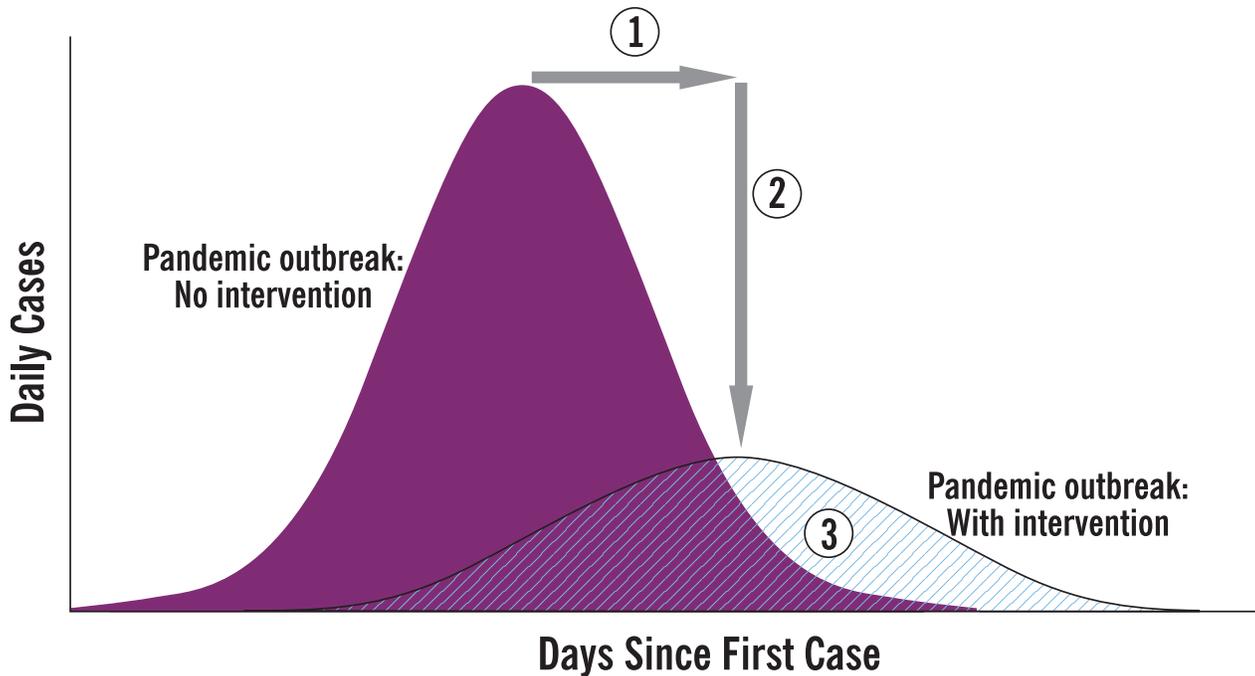
inventories of physical assets (emergency services capacity, inpatient beds, ICU beds, and ventilators) and numbers of healthcare professionals (nurses and physicians). The most prudent approach, therefore, would appear to be to expand medical surge capacity as much as possible while reducing the anticipated demand for services by limiting disease transmission. Delaying a rapid upswing of cases and lowering the epidemic peak to the extent possible would allow a better match between the number of ill persons requiring hospitalization and the nation's capacity to provide medical care for such people (see Figure 1).

The primary strategies for combating influenza are 1) vaccination, 2) treatment of infected individuals and prophylaxis of exposed individuals with influenza antiviral medications, and 3) implementation of infection control and social distancing measures.^{5-7, 8, 13, 14} The single most effective intervention will be vaccination. However, it is highly unlikely that a well-matched vaccine will be available when a pandemic begins unless a vaccine with broad cross-protection is developed.¹⁵⁻¹⁸ With current vaccine technology, pandemic strain vaccine would not become available for at least 4 to 6 months after the start of a pandemic, although this lag time may be reduced in the future. Furthermore, once an effective pandemic vaccine is developed and being produced, it is likely that amounts will be limited due to the production process and will not be sufficient to cover the entire population. Pre-pandemic vaccine may be available at the onset of a pandemic, but there is no guarantee that it will be effective against the emerging pandemic strain. Even if a pre-pandemic vaccine did prove to be effective, projected stockpiles of such a vaccine would be sufficient for only a fraction of the U.S. population.

Figure 1.

Goals of Community Mitigation

- ① Delay outbreak peak
- ② Decompress peak burden on hospitals / infrastructure
- ③ Diminish overall cases and health impacts



These realities mean that we must be prepared to face the first wave of the next pandemic without vaccine—the best countermeasure—and potentially without sufficient quantities of influenza antiviral medications.¹⁹ In addition, it is not known if influenza antiviral medications will be effective against a future pandemic strain. During a pandemic, decisions about how to protect the public before an effective vaccine is available need to be based on scientific data, ethical considerations, consideration of the public’s perspective of the protective measures and the impact on society, and common sense. Evidence to determine the best strategies for protecting people during a pandemic is very limited. Retrospective data from past epidemics and the conclusions drawn from those data need to be examined and analyzed within the context of modern society. Few of those conclusions may be completely generalizable; however, they can inform contemporary planning assumptions. When these assumptions are integrated

into the current mathematical models, the limitations need to be recognized, as they were in a recent Institute of Medicine report.²⁰

This document provides interim pre-pandemic planning guidance for the selection and timing of selected NPIs and recommendations for their use matched to the severity of a future influenza pandemic. While it is not possible, prior to emergence, to predict with certainty the severity of a pandemic, early and rapid characterization of the pandemic virus and initial clusters of human cases may give insight into its potential severity and determine the initial public health response. The main determinant of a pandemic’s severity is its associated mortality.²¹⁻²⁷ This may be defined by case fatality ratio or excess mortality rate—key epidemiological parameters that may be available shortly after the emergence of a pandemic strain from investigations of initial outbreaks or from more routine surveillance

data. Other factors, such as efficiency of transmission, are important for consideration as well.

The Centers for Disease Control and Prevention (CDC) developed this guidance with input from other Federal agencies, key stakeholders, and partners, including a working group of public health officials and other stakeholders (see Appendix 1, Interim Guidance Development Process). A community mitigation framework is proposed that is based upon an early, targeted, layered mitigation strategy involving the directed application of multiple partially effective nonpharmaceutical measures initiated early and maintained consistently during an epidemic wave.^{20, 28-33} These interventions include the following:

1. Isolation and treatment (as appropriate) with influenza antiviral medications of all persons with confirmed or probable pandemic influenza. Isolation may occur in the home or healthcare setting, depending on the severity of an individual's illness and /or the current capacity of the healthcare infrastructure.
2. Voluntary home quarantine of members of households with confirmed or probable influenza case(s) and consideration of combining this intervention with the prophylactic use of antiviral medications, providing sufficient quantities of effective medications exist and that a feasible means of distributing them is in place.
3. Dismissal of students from school (including public and private schools as well as colleges and universities) and school-based activities and closure of childcare programs, coupled with protecting children and teenagers through social distancing in the community to achieve reductions of out-of-school social contacts and community mixing.
4. Use of social distancing measures to reduce contact among adults in the community and workplace, including, for example, cancellation of large public gatherings and alteration of workplace environments and schedules to decrease social density and preserve a healthy workplace to the greatest

extent possible without disrupting essential services. Enable institution of workplace leave policies that align incentives and facilitate adherence with the nonpharmaceutical interventions (NPIs) outlined above.

The effectiveness of individual infection control measures (e.g., cough etiquette, hand hygiene) and the role of surgical masks or respirators in preventing the transmission of influenza is currently unknown. However, cough etiquette and hand hygiene will be recommended universally, and the use of surgical masks and respirators may be appropriate in certain settings (specific community face mask and respirator use guidance is forthcoming as is guidance for workplaces and will be available on www.pandemicflu.gov).

Decisions about what tools should be used during a pandemic should be based on the observed severity of the event, its impact on specific subpopulations, the expected benefit of the interventions, the feasibility of success in modern society, the direct and indirect costs, and the consequences on critical infrastructure, healthcare delivery, and society. The most controversial elements (e.g., prolonged dismissal of students from schools and closure of childcare programs) are not likely to be needed in less severe pandemics, but these steps may save lives during severe pandemics. Just as communities plan and prepare for mitigating the effect of severe natural disasters (e.g., hurricanes), they should plan and prepare for mitigating the effect of a severe pandemic.

The U.S. Government recognizes the significant challenges and social costs that would be imposed by the coordinated application of the measures described above.^{2, 10, 34} It is important to bear in mind, however, that if the experience of the 1918 pandemic is relevant, social distancing and other NPI strategies would, in all likelihood, be implemented in most communities at some point during a pandemic. The potential exists for such interventions to be implemented in an uncoordinated, untimely, and inconsistent manner that would

impose economic and social costs similar to those imposed by strategically implemented interventions but with dramatically reduced effectiveness. The development of clear interim pre-pandemic guidance for planning that outlines a coordinated strategy, based upon the best scientific evidence available, offers communities the best chance to secure the benefits that such strategies may provide. As States and local communities exercise the potential tools for responding to a pandemic, more will be learned about the practical realities of their implementation. Interim recommendations will be updated accordingly.

This document serves as interim public health planning guidance for State, local, territorial, and tribal jurisdictions developing plans for using community mitigation interventions in response to a potential influenza pandemic in the United States. Given the paucity of evidence for the effectiveness of some of the interventions and the potential socioeconomic implications, some interventions may draw considerable disagreement and criticism.²⁰ Some interventions that may be highly useful tools in the framework of a disease control strategy will need to be applied judiciously to balance socioeconomic realities of community functioning. CDC will regularly review this document and, as appropriate, issue updates based on the results from various ongoing historical, epidemiological, and field studies. Response guidance will need to remain flexible and likely will require modification during a pandemic as information becomes available and it can be determined if ongoing pandemic mitigation measures are useful for mitigating the impact of the pandemic. Pandemic planners need to develop requirements for community-level data collection during a pandemic and develop and test a tool or process for accurate real-time and post-wave evaluation of pandemic mitigation measures, with guidelines for modifications.

Communities will need to prepare in advance if they are to accomplish the rapid and coordinated introduction of the measures described while mitigating the potentially significant cascading second- and third-order consequences of the interventions themselves. Cascading second- and

third-order consequences are chains of effects that may arise because of the intervention and may require additional planning and intervention to mitigate. The terms generally refer to foreseeable unintended consequences of intervention. For example, dismissal of students from school classrooms may lead to the second-order effect of workplace absenteeism for child minding. Subsequent workplace absenteeism and loss of household income could be especially problematic for individuals and families living at or near subsistence levels. Workplace absenteeism could also lead to disruption of the delivery of goods and services essential to the viability of the community. If communities are not prepared for these untoward effects, the ability of the public to comply with the proposed measures and, thus, the ability of the measures to reduce suffering and death may be compromised.

Federal, State, local, territorial, and tribal governments and the private sector all have important and interdependent roles in preparing for, responding to, and recovering from a pandemic. To maintain public confidence and to enlist the support of private citizens in disease mitigation efforts, public officials at all levels of government must provide unambiguous and consistent guidance that is useful for planning and can assist all segments of society to recognize and understand the degree to which their collective actions will shape the course of a pandemic. The potential success of community mitigation interventions is dependent upon building a foundation of community and individual and family preparedness. To facilitate preparedness, Pandemic Influenza Community Mitigation Interim Planning Guides have been included as appendices to provide broad but tailored planning guidance for businesses and other employers, childcare programs, elementary and secondary schools, colleges and universities, faith-based and community organizations, and individuals and families (see Appendices 4-9). See also the Department of Homeland Security's *Pandemic Influenza Preparedness, Response and Recovery Guide for Critical Infrastructure and Key Resources* (available at www.pandemicflu.gov/plan/pdf/cikrpandemicinfluenzaguide.pdf).

U.S. and Global Preparedness Planning

The suggested strategies contained in this document are aligned with the World Health Organization (WHO) phases of a pandemic.³⁵ WHO has defined six phases, occurring before and during a pandemic, that are linked to the characteristics of a new influenza virus and its spread through the population (see Appendix 2. WHO Phases of a Pandemic/U.S. Government Stages of a Pandemic). This document specifically provides pre-pandemic planning guidance for the use of NPIs in WHO Phase 6. These phases are described below:

Inter-Pandemic Period

Phase 1: No new influenza virus subtypes have been detected in humans. An influenza virus subtype that has caused human infection may be present in animals. If present in animals, the risk of human disease is considered to be low.

Phase 2: No new influenza virus subtypes have been detected in humans. However, a circulating animal influenza virus subtype poses a substantial risk of human disease.

Pandemic Alert Period

Phase 3: Human infection(s) with a new subtype, but no human-to-human spread, or at most rare instances of spread to a close contact.

Phase 4: Small cluster(s) with limited human-to-human transmission but spread is highly localized, suggesting that the virus is not well adapted to humans.

Phase 5: Larger cluster(s) but human-to-human spread still localized, suggesting that the virus is becoming increasingly better adapted to humans, but may not yet be fully transmissible (substantial pandemic risk).

Pandemic Period

Phase 6: Pandemic phase: increased and sustained transmission in general population.

The WHO phases provide succinct statements about the global risk for a pandemic and provide benchmarks against which to measure global response capabilities. However, to describe the U.S. Government's approach to the pandemic response, it is more useful to characterize the stages of an outbreak in terms of the immediate and specific threat a pandemic virus poses to the U.S. population.² The following stages provide a framework for Federal Government actions:

Stage 0: New Domestic Animal Outbreak in At-Risk Country

Stage 1: Suspected Human Outbreak Overseas

Stage 2: Confirmed Human Outbreak Overseas

Stage 3: Widespread Human Outbreaks in Multiple Locations Overseas

Stage 4: First Human Case in North America

Stage 5: Spread throughout United States

Stage 6: Recovery and Preparation for Subsequent Waves

Using the Federal Government's approach, this document provides pre-pandemic planning guidance from Stages 3 through 5 for step-wise escalation of activity, from pre-implementation preparedness, through active preparation for initiation of NPIs, to actual use.

Rationale for Proposed Nonpharmaceutical Interventions

The three major goals of mitigating a community-wide epidemic through NPIs are 1) delay the exponential increase in incident cases and shift the epidemic curve to the right in order to “buy time” for production and distribution of a well-matched pandemic strain vaccine, 2) decrease the epidemic peak, and 3) reduce the total number of incident cases and, thus, reduce morbidity and mortality in the community (Figure 1). These three major goals of epidemic mitigation may all be accomplished by focusing on the single goal of saving lives by reducing transmission. NPIs may help reduce influenza transmission by reducing contact between sick persons and uninfected persons, thereby reducing the number of infected persons. Reducing the number of persons infected will also lessen the need for healthcare services and minimize the impact of a pandemic on the economy and society. The surge of need for medical care associated with a poorly mitigated severe pandemic can be only partially addressed by increasing capacity within hospitals and other care settings. Thus, reshaping the demand for healthcare services by using NPIs is an important component of the overall strategy for mitigating a severe pandemic

Principles of Disease Transmission

Decreasing the Basic Reproductive number, R_0

The basic reproductive number, R_0 , is the average number of new infections that a typical infectious person will produce during the course of his/her infection in a fully susceptible population in the absence of interventions.³⁶⁻³⁸ R_0 is not an intrinsic property of the infectious agent but is rather an epidemic characteristic of the agent acting within a specific host within a given milieu. For any

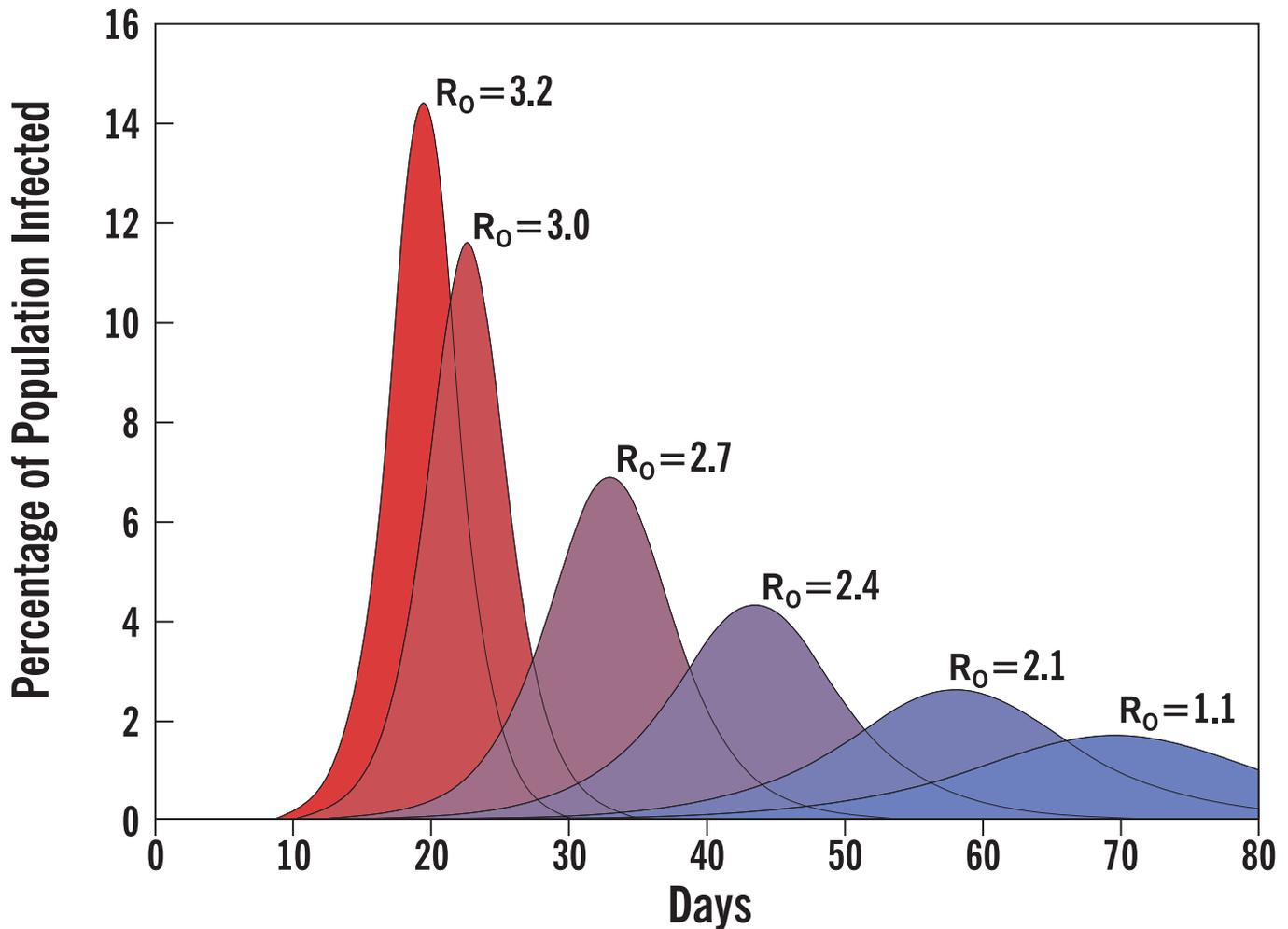
given duration of infection and contact structure, R_0 provides a measure of the transmissibility of an infectious agent. Alterations in the pathogen, the host, or the contact networks can result in changes in R_0 and thus in the shape of the epidemic curve. Generally speaking, as R_0 increases, epidemics have a sharper rise in the case curve, a higher peak illness rate (clinical attack rate), a shorter duration, and a higher percentage of the population infected before the effects of herd immunity begin to exert an influence (in homogeneous contact networks, herd immunity effects should dominate when the percentage of the population infected or otherwise rendered immune is equivalent to $1 - 1/R_0$). R_t is the change in the reproductive number at a given point in time. Thus, as shown in Figure 2, decreasing R_t by decreasing host susceptibility (through vaccination or the implementation of individual infection control measures) or reducing transmission by diminishing the number of opportunities for exposure and transmission (through the implementation of community-wide NPIs) will achieve the three major goals of epidemic mitigation.³⁹ Mathematical modeling of pandemic influenza scenarios in the United States suggests that pandemic mitigation strategies utilizing NPIs separately and in combination with medical countermeasures may decrease the R_t .^{20, 28-31, 40} This potential to reduce R_t is the rationale for employing early, targeted, and layered community-level NPIs as key components of the public health response.

Influenza: Infectiousness and Transmissibility

Assuming the pandemic influenza strain will have transmission dynamics comparable to those for seasonal influenza and recent pandemic influenza strains, the infection control challenges posed will be

Figure 2.

Effect of R_0 on Epidemic Curves



considerable. Factors responsible for these challenges include 1) a short incubation period (average of 2 days, range 1-4 days); 2) the onset of viral shedding (and presumably of infectiousness) prior to the onset of symptoms; and 3) the lack of specific clinical signs and symptoms that can reliably discriminate influenza infections from other causes of respiratory illness.^{41, 42} Although the hallmarks of a pandemic strain will not be known until emergence, patients with influenza may shed virus prior to the onset of clinical symptoms and may be infectious on the day before illness onset. Most people infected with influenza develop symptomatic illness (temperature of 100.4° F or greater, plus cough or sore throat), and the amount of virus they shed correlates with their temperature; however, as many as one-third to one-

half of those who are infected may either have very mild or asymptomatic infection. This possibility is important because even seemingly healthy individuals with influenza infection as well as those with mild symptoms who are not recognized as having influenza could be infectious to others.

Early, Targeted Implementation of Interventions

The potential for significant transmission of pandemic influenza by asymptomatic or minimally symptomatic individuals to their contacts suggests that efforts to limit community transmission that rely on targeting only symptomatic individuals would result in diminished ability to mitigate the effects of

a pandemic. Additionally, the short intergeneration time of influenza disease suggests that household members living with an ill individual (who are thus at increased risk of infection with pandemic virus) would need to be identified rapidly and targeted for appropriate intervention to limit community spread.^{20, 28-31, 40} Recent estimates have suggested that while the reproductive number for most strains of influenza is less than 2, the intergeneration time may be as little as 2.6 days. These parameters predict that in the absence of disease mitigation measures, the number of cases of epidemic influenza will double about every 3 days, or about a tenfold increase every 1-2 weeks. Given the potential for exponential growth of a pandemic, it is reasonable to expect that the timing of interventions will be critical. Planning for community response that is predicated on reactive implementation of these measures may limit overall effectiveness. Measures instituted earlier in a pandemic would be expected to be more effective than the same measures instituted after a pandemic is well established. Although subject to many limitations, mathematical models that explored potential source mitigation strategies that make use of vaccine, antiviral medications, and other infection control and social distancing measures for use in an influenza outbreak identified critical time thresholds for success.^{20, 28, 31} These results suggest that the effectiveness of pandemic mitigation strategies will erode rapidly as the cumulative illness rate prior to implementation climbs above 1 percent of the population in an affected area. Thus, pre-pandemic, scenario-based contingency planning for the early, targeted use of NPIs likely provides the greatest potential for an effective public health response.

To summarize, isolation of ill individuals will reduce the onward transmission of disease after such individuals are identified. However, influenza is a disease in which infected persons may shed virus prior to onset of symptoms and thus are potentially infectious for approximately 1 day before becoming symptomatic. In addition, not all infected individuals will be identified because mild or asymptomatic cases may be relatively common. Isolation strategies are thus, at best, a partial solution. Similarly, voluntary quarantine of members of households with ill persons

will facilitate the termination of transmission chains, but quarantine strategies are limited to the extent that they can be implemented only after cases are identified. Consequently, only a percentage of transmission chains will be interrupted in this fashion. Given the very short generation times (time between a primary and secondary case) observed with influenza and the fact that peak infectiousness occurs around the time of symptom onset, the identification of cases and simultaneous implementation of isolation and quarantine must occur very rapidly or the efficacy of these strategies will erode significantly.

Antiviral Therapy/Prophylaxis

Four approved influenza antiviral agents are available in the United States: amantadine, rimantadine, zanamivir, and oseltamivir. The role of influenza antiviral medications as therapy for symptomatic individuals is primarily to improve individual outcomes not to limit the further transmission of disease; although, recent clinical trials have demonstrated that prophylaxis of household contacts of symptomatic individuals with neuraminidase inhibitors can reduce household transmission.⁴³⁻⁴⁸

Current antiviral medication stockpiles are thought to be inadequate to support antiviral prophylaxis of members of households with ill individuals.^{49, 50} Moreover, the feasibility of rapidly (within 48 hours after exposure) providing these medications to ill individuals and those who live in household with ill individuals has not been tested and mechanisms to support such distribution need to be developed. As with the use of antiviral medications for treatment, concerns exist regarding the emergence of resistance if the use of antiviral medications for prophylaxis is widespread.^{51, 52} Although mathematical models illustrate the additive effects that antiviral prophylaxis offers in reducing disease transmission, these challenges must be addressed to make this a realistic measure for implementation during a pandemic.²⁰ Future updates of this guidance will address feasibility concerns and incorporate any new recommendations regarding use of antiviral prophylaxis for members of households with ill individuals.

Targeting Interventions by Exploiting Heterogeneities in Disease Transmission

Our social connectedness provides a disease transmission network for a pandemic to spread.⁵⁰ Variation exists with respect to individual social connectedness and contribution to disease transmission. Such a distribution is characteristic of a “scale-free” network. A scale-free network is one in which connectivity between nodes follows a distribution in which there are a few highly connected nodes among a larger number of less connected nodes. Air travel provides an example of this concept. In this example, a relatively small number of large hub airports are highly connected with large numbers of originating and connecting flights from a much larger number of small regional airports with a limited number of flights and far lesser degree of connectedness to other airports. Because of the differences in connectivity, the closure of a major hub airport, compared with closure of a small regional airport, would have a disproportionately greater effect on air travel. Given the variation of social connectedness and its contribution to the formation of disease transmission networks, it is useful to identify the nodes of high connectivity since eliminating transmission at these nodes could most effectively reduce disease transmission.

Social Density

One measure for decreasing transmission of an influenza virus is by increasing the distances among people in work, community, and school settings.³¹ Schools and pre-schools represent the most socially dense of these environments. Social density is greatest in pre-school classrooms, with guidelines for occupancy density specifying 35-50 square feet per child.^{60, 61} Published criteria for classroom size based upon the number of students and one teacher recommend an elementary school and high school classroom density of 49 and 64 square feet per person, respectively.⁶² There is more space per person in work and healthcare settings, with high variability from one setting to another; for example, occupancy density in hospitals is about 190 square feet per person.⁶³ Office buildings and large retail buildings

have an average occupational density of 390-470 square feet per person.^{64, 65} Homes represent the least socially dense environment (median occupancy density of 734 square feet per person in single-family homes).⁶⁶

Public transportation, including subways and transit buses, represents another socially dense environment. There were on average 32.8 million unlinked passenger trips each weekday for all public transportation across the United States in 2004—nearly 20 million of which were by bus.⁶⁷ More than half these 32.8 million passenger trips are work related (54 percent) and about 15 percent of these trips are school related.⁶⁸ Each day, 144,000 public transit vehicles, including 81,000 buses, are in use.

More than half the children attending school (K-12) in the United States travel on a school bus—that equates to an estimated 58 million person trips daily (to school and back home).⁶⁹ The number of schoolchildren traveling via school bus and via public transportation during a school day is twice the number of people taking all public transportation in the United States in terms of number of trips and number of individuals during a weekday.

Targeting Schools, Childcare, and Children

Biological, social, and maturational factors make children especially important in the transmission of influenza. Children without pre-existing immunity to circulating influenza viruses are more susceptible than adults to infection and, compared with adults, are responsible for more secondary transmission within households.^{70, 71} Compared with adults, children usually shed more influenza virus, and they shed virus for a longer period. They also are not skilled in handling their secretions, and they are in close proximity with many other children for most of the day at school. Schools, in particular, clearly serve as amplification points of seasonal community influenza epidemics, and children are thought to play a significant role in introducing and transmitting influenza virus within their households.^{20, 27, 70-76, 78} A recent clinical trial demonstrated that removing a comparatively modest number of school children

from the transmission pool through vaccination (vaccinating 47 percent of students with a live attenuated vaccine whose efficacy was found in a separate trial to be no greater than 57 percent) resulted in significant reductions in influenza-related outcomes in households of children (whether vaccinated or unvaccinated) attending intervention schools.⁷⁷

Therefore, given the disproportionate contribution of children to disease transmission and epidemic amplification, targeting their social networks both within and outside of schools would be expected to disproportionately disrupt influenza spread. Given that children and teens are together at school for a significant portion of the day, dismissal of students from school could effectively disrupt a significant portion of influenza transmission within these age groups. There is evidence to suggest that school closure can in fact interrupt influenza spread. While the applicability to a U.S. pandemic experience is not clear, nationwide school closure in Israel during an influenza epidemic resulted in significant decreases in the diagnoses of respiratory infections (42 percent), visits to physicians (28 percent) and emergency departments (28 percent), and medication purchases (35 percent).⁵⁶ The New York City Department of Health and Mental Hygiene recently examined the impact of routine school breaks (e.g., winter break) on emergency department visits for influenza-like illness from 2001 to 2006. Emergency department visits for complaints of febrile illness among school-age children (aged 5 to 17 years) typically declined starting 2-3 days after a school break began, remained static during the school break, and then increased within several days after school recommenced. A similar pattern was not seen in the adult age group.⁷⁸

Dismissal of students from school could eliminate a potential amplifier of transmission. However, re-congregation and social mixing of children at alternate settings could offset gains associated with disruption of their social networks in schools. For this reason, dismissal of students from schools and, to the extent possible, protecting children and teenagers through social distancing in the community, to include reductions of out-of-school social contacts and community mixing, are proposed as a bundled

strategy for disrupting their social networks and, thus, the associated disease transmission pathways for this age group.⁷⁹

Targeting Adults—Social Distancing at Work and in the Community

Eliminating schools as a focus of epidemic amplification and reducing the social contacts for children and teens outside the home will change the locations and dynamics of influenza virus transmission. The social compartments within which the majority of disease transmission will likely take place will be the home and workplace, and adults will play a more important role in sustaining transmission chains.^{20, 53, 73} Disrupting adult-to-adult transmission will offer additional opportunities to suppress epidemic spread. The adoption by individuals of infection control measures, such as hand hygiene and cough etiquette, in the community and workplace will be strongly encouraged.

In addition, adults may further decrease their risk of infection by practicing social distancing and minimizing their non-essential social contacts and exposure to socially dense environments. Low-cost and sustainable social distancing strategies can be adopted by individuals within their community (e.g., going to the grocery store once a week rather than every other day, avoiding large public gatherings) and at their workplace (e.g., spacing people farther apart in the workplace, teleworking when feasible, substituting teleconferences for meetings) for the duration of a community outbreak. Employers will be encouraged to establish liberal/unscheduled leave policies, under which employees may use available paid or unpaid leave without receiving prior supervisory approval so that workers who are ill or have ill family members are excused from their responsibilities until their or their family members' symptoms have resolved. In this way, the amount of disease transmission that occurs in the workplace can be minimized, making the workplace a safer environment for other workers.

Healthcare workers may be prime candidates for targeted antiviral prophylaxis once supplies of the drugs are adequate to support this use. Moreover, beyond the healthcare arena, employers who operate

or contract for occupational medical services could consider a cache of antiviral drugs in anticipation of a pandemic and provide prophylactic regimens to employees who work in critical infrastructure businesses, occupy business-critical roles, or hold jobs that put them at repeated high risk of exposure to the pandemic virus. This use of antiviral drugs may be considered for inclusion in a comprehensive pandemic influenza response and may be coupled with NPIs. Strategies ensuring workplace safety will increase worker confidence and may discourage unnecessary absenteeism.

Value of Partially Effective Layered Interventions

Pandemic mitigation strategies generally include 1) case containment measures, such as voluntary case isolation, voluntary quarantine of members of households with ill persons, and antiviral treatment/prophylaxis; 2) social distancing measures, such as dismissal of students from classrooms and social distancing of adults in the community and at work; and 3) infection control measures, including hand hygiene and cough etiquette. Each of these interventions may be only partially effective in limiting transmission when implemented alone.

To determine the usefulness of these partially effective measures alone and in combination, mathematical models were developed to assess these types of interventions within the context of contemporary social networks. The “Models of Infectious Disease Agents Study” (MIDAS), funded by the National Institutes of Health, has been developing agent-based computer simulations of pandemic influenza outbreaks with various epidemic parameters, strategies for using medical countermeasures, and patterns of implementation of community-based interventions (case isolation, household quarantine, child and adult social distancing through school or workplace closure or restrictions, and restrictions on travel).^{20, 28-30, 32, 39, 40}

Mathematical modeling conducted by MIDAS participants demonstrates general consistency in outcome for NPIs and suggests the following within the context of the model assumptions:

- Interventions implemented in combination, even with less than complete levels of public adherence, are effective in reducing transmission of pandemic influenza virus, particularly for lower values of R_0 .
- School closure and generic social distancing are important components of a community mitigation strategy because schools and workplaces are significant compartments for transmission.
- Simultaneous implementation of multiple tools that target different compartments for transmission is important in limiting transmission because removing one source of transmission may simply make other sources relatively more important.
- Timely intervention may reduce the total number of persons infected with pandemic influenza.

Each of the models generally suggest that a combination of targeted antiviral medications and NPIs can delay and flatten the epidemic peak, but the degree to which they reduce the overall size of the epidemic varies. Delay of the epidemic peak is critically important because it allows additional time for vaccine development and antiviral production. However, these models are not validated with empirical data and are subject to many limitations.²⁰

Supporting evidence for the role of combinations of NPIs in limiting transmission can also be found in the preliminary results from several historical analyses.²⁰ One statistical model being developed based on analysis of historical data for the use of various combinations of selected NPIs in U.S. cities during the 1918 pandemic demonstrates a significant association between early implementation of these measures by cities and reductions in peak death rate.^{80, 81}

Taken together, these strands of evidence are consistent with the hypothesis that there may be benefit in limiting or slowing the community transmission of a pandemic virus by the use of combinations of partially effective NPIs. At the present time, this hypothesis remains unproven, and more work is needed before its validity can be established.

Pre-pandemic Planning: The Pandemic Severity Index

Appropriate matching of the intensity of intervention to the severity of a pandemic is important to maximize the available public health benefit that may result from using an early, targeted, and layered strategy while minimizing untoward secondary effects. To assist pre-pandemic planning, this interim guidance introduces the concept of a Pandemic Severity Index based primarily on case fatality ratio²³⁻²⁷, a measurement that is useful in estimating the severity of a pandemic on a population level and which may be available early in a pandemic for small clusters and outbreaks. Excess mortality rate may also be available early and may supplement and inform the determination of the Pandemic Severity Index.⁸² Pandemic severity is described within five discrete categories of increasing severity (Category 1 to Category 5). Other epidemiologic features that are relevant in overall analysis of mitigation plans include total illness rate, age-specific illness and mortality rates, the reproductive number, intergeneration time, and incubation period. However, it is unlikely that estimates will be available for most of these parameters during the early stages of a pandemic; thus, they are not as useful from a planning perspective.

The Pandemic Severity Index provides U.S. communities a tool for scenario-based contingency planning to guide pre-pandemic planning efforts. Upon declaration by WHO of having entered the Pandemic Period (Phase 6) and further determination of U.S. Government Stage 3, 4, or 5, the CDC's Director shall designate the category of the emerging pandemic based on the Pandemic Severity Index and consideration of other available information. Pending this announcement, communities facing the imminent arrival of pandemic disease will be able to define

which pandemic mitigation interventions are most indicated for implementation based on the level of pandemic severity.

Multiple parameters may ultimately provide a more complete characterization of a pandemic. The age-specific and total illness and mortality rates, reproductive number, intergeneration time, and incubation period as well as population structure and healthcare infrastructure are important factors in determining pandemic impact. Although many factors may influence the outcome of an event, it is reasonable to maintain a single criterion for classification of severity for the purposes of guiding contingency planning. If additional epidemiologic characteristics become well established during the course of the next pandemic through collection and analysis of surveillance data, then local jurisdictions may develop a subset of scenarios, depending upon, for example, age-specific mortality rates.

Table 1 provides a categorization of pandemic severity by case fatality ratio—the key measurement in determining the Pandemic Severity Index—and excess mortality rate. In addition, Table 1 displays ranges of illness rates with potential numbers of U.S. deaths per category, with recent U.S. pandemic experience and U.S. seasonal influenza to provide historical context. Figure 3a plots prior U.S. pandemics from the last century and a severe annual influenza season based on case fatality ratio and illness rate and demonstrates the great variability in pandemics based on these parameters (and the clear distinctiveness of pandemics from even a severe annual influenza season). Figure 3b demonstrates that the primary factor determining pandemic severity is case fatality ratio. Incremental increases in case

Table 1. Pandemic Severity Index by Epidemiological Characteristics

| Characteristics | Pandemic Severity Index (PSI) | | | | |
|--|---|-----------------|------------------|----------------------|---------------|
| | Category 1 | Category 2 | Category 3 | Category 4 | Category 5 |
| Case Fatality Ratio (percentage) | <0.1 | 0.1-<0.5 | 0.5-<1.0 | 1.0-<2.0 | ≥2.0 |
| Excess Death Rate (per 100,000) | <30 | 30-<150 | 150-<300 | 300-<600 | ≥600 |
| Illness Rate (percentage of the population) | 20-40 | 20-40 | 20-40 | 20-40 | 20-40 |
| Potential Number of Deaths (based on 2006 U.S. population) | <90,000 | 90,000-<450,000 | 450,000-<900,000 | 900,000-<1.8 million | ≥1.8 million |
| 20 th Century U.S.Experience | Seasonal Influenza (illness rate 5-20%) | 1957,1968 | None | None | 1918 Pandemic |

fatality ratio result in proportionally greater mortality in comparison to increasing illness rates, which result in proportionally much smaller increases in mortality. Figure 4 provides a graphic depiction of the U.S. Pandemic Severity Index by case fatality ratio, with ranges of projected U.S. deaths at a constant 30 percent illness rate and without mitigation by any intervention.

Data on case fatality ratio and excess mortality in the early course of the next pandemic will be collected during outbreak investigations of initial clusters of human cases, and public health officials may make use of existing influenza surveillance systems once widespread transmission starts. However, it is possible that at the onset of an emerging pandemic, very limited information about cases and deaths will be known. Efforts now to develop decision algorithms based on partial data and efforts to improve global surveillance systems for influenza are needed.

Figure 3A. Projected Mortality* of a Modern Influenza Pandemic Compared with that of 20th Century Pandemics (1918, 1957, 1968)

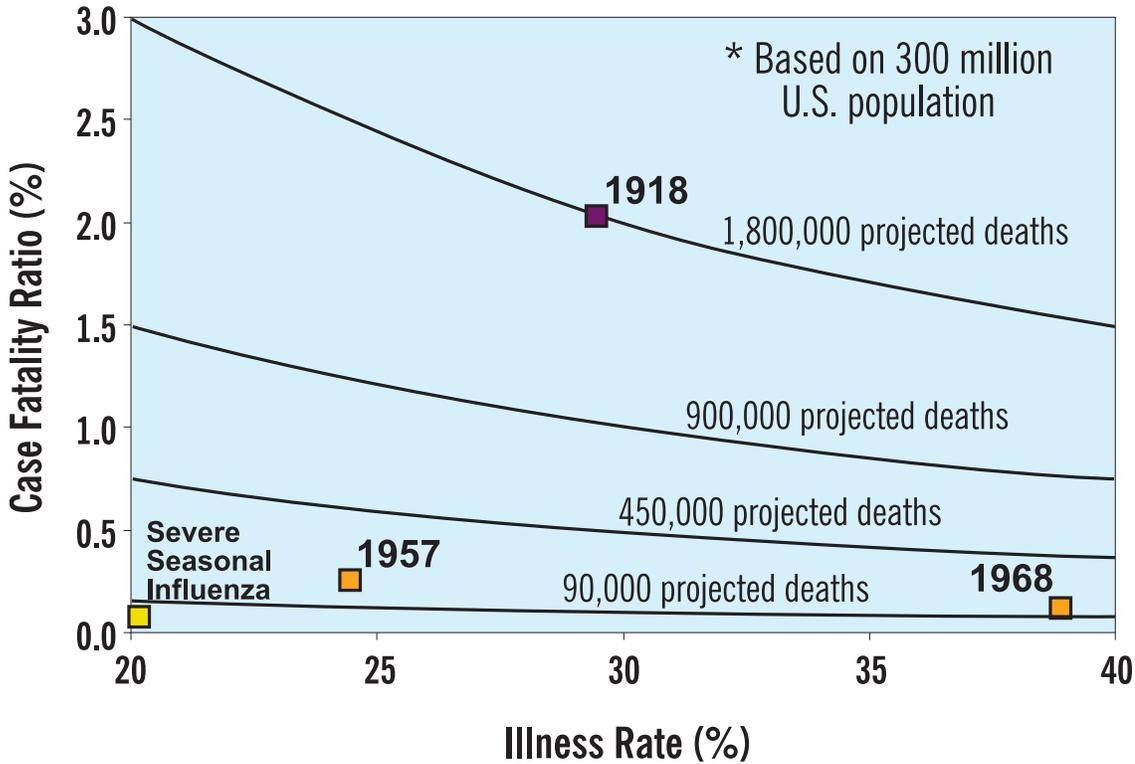


Figure 3B. Pandemic Severity Categories as Determined by Differences in Case Fatality Ratio

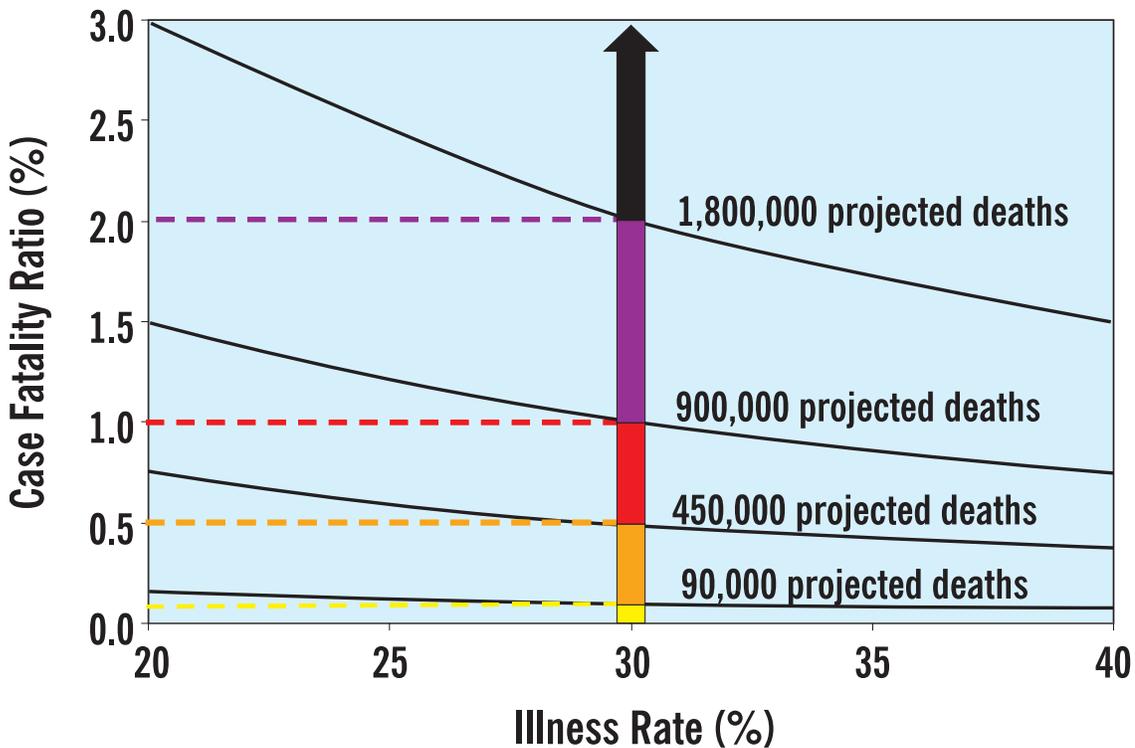
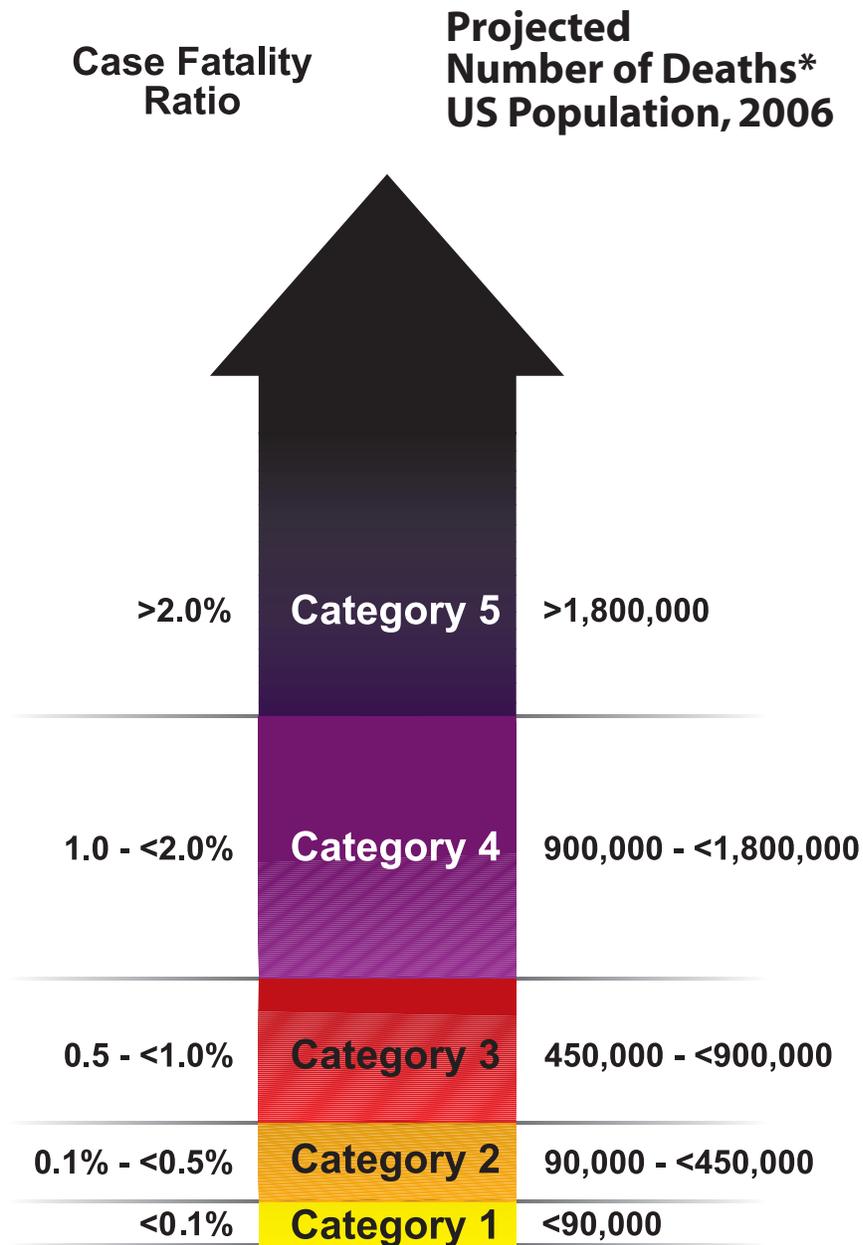


Figure 4. Pandemic Severity Index



Assumes 30% Illness Rate and Unmitigated Pandemic Without Interventions

Use of Nonpharmaceutical Interventions by Pandemic Severity Category

This section provides interim pre-pandemic planning recommendations for use of pandemic mitigation interventions to limit community transmission. These planning recommendations are likely to evolve as more information about their effectiveness and feasibility becomes available. To minimize economic and social costs, it will be important to judiciously match interventions to the pandemic severity level. However, at the time of an emerging pandemic, depending on the location of the first detected cases, there may be scant information about the number of cases and deaths resulting from infection with the virus. Although surveillance efforts may initially only detect the “herald” cases, public health officials may choose to err on the side of caution and implement interventions based on currently available data and iteratively adjust as more accurate and complete data become available. These pandemic mitigation measures include the following:

1. Isolation and treatment (as appropriate) with influenza antiviral medications of all persons with confirmed or probable pandemic influenza. Isolation may occur in the home or healthcare setting, depending on the severity of an individual’s illness and /or the current capacity of the healthcare infrastructure.
2. Voluntary home quarantine of members of households with confirmed or probable influenza case(s) and consideration of combining this intervention with the prophylactic use of antiviral medications, providing sufficient quantities of effective medications exist and that a feasible means of distributing them is in place.
3. Dismissal of students from school (including public and private schools as well as colleges and

universities) and school-based activities and closure of childcare programs, coupled with protecting children and teenagers through social distancing in the community to achieve reductions of out-of-school social contacts and community mixing.

4. Use of social distancing measures to reduce contact between adults in the community and workplace, including, for example, cancellation of large public gatherings and alteration of workplace environments and schedules to decrease social density and preserve a healthy workplace to the greatest extent possible without disrupting essential services. Enable institution of workplace leave policies that align incentives and facilitate adherence with the nonpharmaceutical interventions (NPIs) outlined above.

Planning for use of these NPIs is based on the Pandemic Severity Index, which may allow more appropriate matching of the interventions to the magnitude of the pandemic. These recommendations are summarized in Table 2. All interventions should be combined with infection control practices, such as good hand hygiene and cough etiquette. In addition, the use of personal protective equipment, such as surgical masks or respirators, may be appropriate in some cases, and guidance on community face mask and respirator use will be forthcoming. Guidance on infection control measures, including those for workplaces, may be accessed at www.pandemicflu.gov. For Category 4 or Category 5 pandemics, a planning recommendation is made for use of all listed NPIs (Table 2). In addition, planning for dismissal of students from schools and school-based activities and closure of childcare programs, in combination with means to reduce out-of-school social contacts and community mixing for these children, should

Table 2. Summary of the Community Mitigation Strategy by Pandemic Severity

| Pandemic Severity Index | | | |
|---|--|--|--|
| Interventions* by Setting | 1 | 2 and 3 | 4 and 5 |
| Home Voluntary isolation of ill at home (adults and children); combine with use of antiviral treatment as available and indicated | Recommend†§ | Recommend†§ | Recommend†§ |
| Voluntary quarantine of household members in homes with ill persons¶ (adults and children); consider combining with antiviral prophylaxis if effective, feasible, and quantities sufficient | Generally not recommended | Consider** | Recommend** |
| School Child social distancing -dismissal of students from schools and school based activities, and closure of child care programs -reduce out-of-school social contacts and community mixing | Generally not recommended Generally not recommended | Consider: ≤4 weeks†† Consider: ≤4 weeks†† | Recommend: ≤12 weeks§§ Recommend: ≤12 weeks§§ |
| Workplace / Community Adult social distancing -decrease number of social contacts (e.g., encourage teleconferences, alternatives to face-to-face meetings) -increase distance between persons (e.g., reduce density in public transit, workplace) -modify postpone, or cancel selected public gatherings to promote social distance (e.g., postpone indoor stadium events, theatre performances) -modify work place schedules and practices (e.g., telework, staggered shifts) | Generally not recommended Generally not recommended Generally not recommended Generally not recommended | Consider Consider Consider Consider | Recommend Recommend Recommend Recommend |

Generally Not Recommended = Unless there is a compelling rationale for specific populations or jurisdictions, measures are generally not recommended for entire populations as the consequences may outweigh the benefits.

Consider = Important to consider these alternatives as part of a prudent planning strategy, considering characteristics of the pandemic, such as age-specific illness rate, geographic distribution, and the magnitude of adverse consequences. These factors may vary globally, nationally, and locally.

Recommended = Generally recommended as an important component of the planning strategy.

*All these interventions should be used in combination with other infection control measures, including hand hygiene, cough etiquette, and personal protective equipment such as face masks. Additional information on infection control measures is available at www.pandemicflu.gov.

†This intervention may be combined with the treatment of sick individuals using antiviral medications and with vaccine campaigns, if supplies are available

§Many sick individuals who are not critically ill may be managed safely at home

¶The contribution made by contact with asymptotically infected individuals to

disease transmission is unclear. Household members in homes with ill persons may be at increased risk of contracting pandemic disease from an ill household member. These household members may have asymptomatic illness and may be able to shed influenza virus that promotes community disease transmission. Therefore, household members of homes with sick individuals would be advised to stay home.

**To facilitate compliance and decrease risk of household transmission, this intervention may be combined with provision of antiviral medications to household contacts, depending on drug availability, feasibility of distribution, and effectiveness; policy recommendations for antiviral prophylaxis are addressed in a separate guidance document.

††Consider short-term implementation of this measure—that is, less than 4 weeks.

§§Plan for prolonged implementation of this measure—that is, 1 to 3 months; actual duration may vary depending on transmission in the community as the pandemic wave is expected to last 6-8 weeks.

encompass up to 12 weeks of intervention in the most severe scenarios. This approach to pre-pandemic planning will provide a baseline of readiness for community response even if the actual response is shorter. Recommendations for use of these measures for pandemics of lesser severity may include a subset of these same interventions and, possibly, suggestions that they be used for shorter durations, as in the case of the social distancing measures for children.

For Category 2 or Category 3 pandemics, planning for voluntary isolation of ill persons is recommended, whereas other measures (voluntary quarantine of household contacts, social distancing measures for children and adults) are to be implemented only if local decision-makers have determined that characteristics of the pandemic in their community warrant these additional mitigation measures. However, within these categories, pre-pandemic planning for social distancing measures for children should be undertaken with a focus on a duration of 4 weeks or less, distinct from the longer timeframe recommended for pandemics with a greater Pandemic Severity Index. For Category 1 pandemics, only voluntary isolation of ill persons is recommended on a community-wide basis, although local communities may still choose to tailor their response to Category 1-3 pandemics differently by applying NPIs on the basis of local epidemiologic parameters, risk assessment, availability of countermeasures, and consideration of local healthcare surge capacity. Thus, from a pre-pandemic planning perspective for Category 1, 2, and 3 pandemics, capabilities for both assessing local public health capacity and healthcare surge, delivering countermeasures, and implementing these measures in full and in combination should be assessed.

Nonpharmaceutical Interventions

Voluntary Isolation of Ill Persons

The goal of this intervention is to reduce transmission by reducing contact between persons who are ill and those who are not. Ill individuals not requiring hospitalization would be requested to remain at home voluntarily for the infectious period, approximately 7-10 days after symptom onset. This would usually

be in their homes, but could be in a home of a friend or relative. Voluntary isolation of ill children and adults at home is predicated on the assumption that many ill individuals who are not critically ill can, and will need to be cared for in the home. In addition, this intervention may be combined with the use of influenza antiviral medications for treatment (as appropriate), as long as such medications are effective and sufficient in quantity and that feasible plans and protocols for distribution are in place.

Requirements for success include prompt recognition of illness, appropriate use of hygiene and infection control practices in the home setting (specific guidance is forthcoming and will be available on www.pandemicflu.gov); measures to promote voluntary compliance (e.g., timely and effective risk communications); commitment of employers to support the recommendation that ill employees stay home; and support for the financial, social, physical, and mental health needs of patients and caregivers. In addition, ill individuals and their household members need clear, concise information about how to care for an ill individual in the home and when and where to seek medical care. Special consideration should be made for persons who live alone, as many of these individuals may be unable to care for themselves if ill.

Voluntary Quarantine of Household Members of Ill Persons

The goal of this intervention is to reduce community transmission from members of households in which there is a person ill with pandemic influenza. Members of households in which there is an ill person may be at increased risk of becoming infected with a pandemic influenza virus. As determined on the basis of known characteristics of influenza, a significant proportion of these persons may shed virus and present a risk of infecting others in the community despite having asymptomatic or only minimally symptomatic illness that is not recognized as pandemic influenza disease. Thus, members of households with ill individuals may be recommended to stay home for an incubation period, 7 days (voluntary quarantine) following the time of symptom onset in the household member. If other

family members become ill during this period, the recommendation is to extend the time of voluntary home quarantine for another incubation period, 7 days from the time that the last family member becomes ill. In addition, consideration may be given to combining this intervention with provision of influenza antiviral medication to persons in quarantine if such medications are effective and sufficient in quantity and if a feasible means of distributing them is in place.

Requirements for success of this intervention include the prompt and accurate identification of an ill person in the household, voluntary compliance with quarantine by household members, commitment of employers to support the recommendation that employees living in a household with an ill individual stay home, the ability to provide needed support to households that are under voluntary quarantine, and guidance for infection control in the home. Additionally, adherence to ethical principals in use of quarantine during pandemics, along with proactive anti-stigma measures should be assured.^{83, 84}

Child Social Distancing

The goal of these interventions is to protect children and to decrease transmission among children in dense classroom and non-school settings and, thus, to decrease introduction into households and the community at large. Social distancing interventions for children include dismissal of students from classrooms and closure of childcare programs, coupled with protecting children and teenagers through social distancing in the community to achieve reductions of out-of-school social contacts and community mixing. Childcare facilities and schools represent an important point of epidemic amplification, while the children themselves, for reasons cited above, are thought to be efficient transmitters of disease in any setting. The common sense desire of parents to protect their children by limiting their contacts with others during a severe pandemic is congruent with public health priorities, and parents should be advised that they could protect their children by reducing their social contacts as much as possible.

However, it is acknowledged that maintaining the strict confinement of children during a pandemic would raise significant problems for many families and may cause psychosocial stress to children and adolescents. These considerations must be weighed against the severity of a given pandemic virus to the community at large and to children in particular. Risk of introduction of an infection into a group and subsequent transmission among group members is directly related to the functional number of individuals in the group. Although the available evidence currently does not permit the specification of a “safe” group size, activities that recreate the typical density and numbers of children in school classrooms are clearly to be avoided. Gatherings of children that are comparable to family-size units may be acceptable and could be important in facilitating social interaction and play behaviors for children and promoting emotional and psychosocial stability.

A recent study of children between the ages of 25 and 36 months found that children in group care with six or more children were 2.2 times as likely to have an upper respiratory tract illness as children reared at home or in small-group care (defined as fewer than six children).⁸⁵ If a recommendation for social distancing of children is advised during a pandemic and families must nevertheless group their children for pragmatic reasons, it is recommended that group sizes be held to a minimum and that mixing between such groups be minimized (e.g., children should not move from group to group or have extended social contacts outside the designated group).

Requirements for success of these interventions include consistent implementation among all schools in a region being affected by an outbreak of pandemic influenza, community and parental commitment to keeping children from congregating out of school, alternative options for the education and social interaction of the children, clear legal authorities for decisions to dismiss students from classes and identification of the decision-makers, and support for parents and adolescents who need to stay home from work. Interim recommendations for pre-pandemic planning for this intervention include a three-tiered

strategy: 1) no dismissal of students from schools or closure of childcare facilities in a Category 1 pandemic, 2) short-term (up to 4 weeks) cancellation of classes and closure of childcare facilities during a Category 2 or Category 3 pandemic, and 3) prolonged (up to 12 weeks) dismissal of students and closure of childcare facilities during a severe influenza pandemic (Category 4 or Category 5). The conceptual thinking behind this recommendation is developed more fully in Section VII, *Duration of Implementation of NPIs*.

Colleges and universities present unique challenges in terms of pre-pandemic planning because many aspects of student life and activity encompass factors that are common to both the child school environment (e.g., classroom/dormitory density) and the adult sphere (e.g., commuting longer distances for university attendance and participating in activities and behaviors associated with an older student population). Questions remain with regard to the optimal strategy for managing this population during the early stages of an influenza pandemic.

The number of college students in the United States is significant. There are approximately 17 million college students attending both 2- and 4-year universities⁸⁶, a large number of whom live away from home.⁸⁷ Of the 8.3 million students attending public or private 4-year colleges and universities, less than 20 percent live at home with their parents.

At the onset of a pandemic, many parents may want their children who are attending college or university to return home from school. Immediately following the announcement of an outbreak, colleges and universities should prepare to manage or assist large numbers of students departing school and returning home within a short time span. Where possible, policies should be explored that are aligned with the travel of large numbers of students to reunite with family and the significant motivations behind this behavior. Pre-pandemic planning to identify those students likely to return home and those who may require assistance for imminent travel may allow more effective management of the situation. In addition, planning should be considered for those

students who may be unable to return home during a pandemic.

Adult Social Distancing

Social distancing measures for adults include provisions for both workplaces and the community and may play an important role in slowing or limiting community transmission pressure. The goals of workplace measures are to reduce transmission within the workplace and thus into the community at large, to ensure a safe working environment and promote confidence in the workplace, and to maintain business continuity, especially for critical infrastructure. Workplace measures such as encouragement of telework and other alternatives to in-person meetings may be important in reducing social contacts and the accompanying increased risk of transmission. Similarly, modifications to work schedules, such as staggered shifts, may also reduce transmission risk.

Within the community, the goals of these interventions are to reduce community transmission pressures and thus slow or limit transmission. Cancellation or postponement of large gatherings, such as concerts or theatre showings, may reduce transmission risk. Modifications to mass transit policies/ridership to decrease passenger density may also reduce transmission risk, but such changes may require running additional trains and buses, which may be challenging due to transit employee absenteeism, equipment availability, and the transit authority's financial ability to operate nearly empty train cars or buses.

Requirements for success of these various measures include the commitment of employers to providing options and making changes in work environments to reduce contacts while maintaining operations; whereas, within communities, the support of political and business leaders as well as public support is critical.

Triggers for Initiating Use of Nonpharmaceutical Interventions

The timing of initiation of various NPIs will influence their effectiveness. Implementing these measures prior to the pandemic may result in economic and social hardship without public health benefit and may result in compliance fatigue. Conversely, implementing these interventions after extensive spread of a pandemic influenza strain may limit the public health benefits of an early, targeted, and layered mitigation strategy. Identifying the optimal time for initiation of these interventions will be challenging, as implementation likely needs to be early enough to preclude the initial steep upslope in case numbers and long enough to cover the peak of the anticipated epidemic curve while avoiding intervention fatigue. In this document, the use of these measures is aligned with declaration by WHO of having entered the Pandemic Period Phase 6 and a U.S. Government declaration of Stage 3, 4, or 5.

Case fatality ratio and excess mortality rates may be used as a measure of the potential severity of a pandemic and, thus, suggest the appropriate nonpharmaceutical tools; however, mortality estimates alone are not suitable trigger points for action. This guidance suggests the primary activation trigger for initiating interventions be the arrival and transmission of pandemic virus. This trigger is best defined by a laboratory-confirmed cluster of infection with a novel influenza virus and evidence of community transmission (i.e., epidemiologically linked cases from more than one household). Other factors that will inform decision-making by public health officials include the average number of new infections that a typical infectious person will produce during the course of his/her infection (R_0) and the illness rate. For the recommendations in this interim guidance, trigger points for action assume an R_0 of 1.5-2.0 and an illness rate of 20 percent for adults

and 40 percent for children. In this context, in all categories of pandemic severity, it is recommended that State health authorities activate appropriate interventions (as described in Table 2) when a laboratory-confirmed human pandemic influenza case cluster is reported in their State or region (as appropriate) and there is evidence of community transmission.

Defining the proper geospatial-temporal boundary for this cluster is complex and should recognize that our connectedness as communities goes beyond spatial proximity and includes ease, speed, and volume of travel between geopolitical jurisdictions (e.g., despite the physical distance, Hong Kong, London, and New York City may be more epidemiologically linked to each other than they are to their proximate rural provinces/areas). In this document in order to balance connectedness and the optimal timing referenced above, it is proposed that the geopolitical trigger be defined as the cluster of cases occurring within a U.S. State or proximate epidemiological region (e.g., a metropolitan area that spans more than one State's boundary). It is acknowledged this definition of region is open to interpretation; however, it offers flexibility to State and local decision-makers while underscoring the need for regional coordination in pre-pandemic planning.

From a pre-pandemic planning perspective, the steps between recognition of pandemic threat and the decision to activate a response are critical to successful implementation. Thus, a key component is the development of scenario-specific contingency plans for pandemic response that identify key personnel, critical resources, and processes. To emphasize the importance of this concept, this guidance section on triggers introduces the

terminology of *Alert*, *Standby*, and *Activate*, which reflect key steps in escalation of response action. *Alert* includes notification of critical systems and personnel of their impending activation, *Standby* includes initiation of decision-making processes for imminent activation, including mobilization of resources and personnel, and *Activate* refers to implementation of the specified pandemic mitigation measures. Pre-pandemic planning for use of these interventions should be directed to lessening the transition time between *Alert*, *Standby*, and *Activate*. The speed of transmission may drive the amount of time decision-makers are allotted in each mode, as does the amount of time it takes to truly implement the intervention once a decision is made to activate.

These triggers for implementation of NPIs will be most useful early in a pandemic and are summarized in Table 3. This table provides recommendations arrayed by Pandemic Severity Index and U.S. Government Stage for step-wise escalation of action from *Alert*, to *Standby*, to *Activate*.

For the most severe pandemics (Categories 4 and 5), *Alert* is implemented during WHO Phase 5/U.S. Government Stage 2 (confirmed human outbreak overseas), and *Standby* is initiated during WHO Phase 6/Stage 3 (widespread human outbreaks in multiple locations overseas). *Standby* is maintained through Stage 4 (first human case in North America), with the exception of the State or region in which a laboratory-confirmed human pandemic influenza case

Table 3. Triggers for Implementation of Mitigation Strategy by Pandemic Severity Index and U.S. Government Stages

| Pandemic Severity Index | WHO Phase 6, U.S. Government stage 3* | WHO Phase 6, U.S. Government Stage 4† and First human case in the United States | WHO Phase 6, U.S. Government Stage 5§ and First laboratory confirmed cluster in state or region¶ |
|-------------------------|---------------------------------------|---|--|
| 1 | Alert | Standby | Activate |
| 2 and 3 | Alert | Standby | Activate |
| 4 and 5 | Standby** | Standby/Activate†† | Activate |

Alert: Notification of critical systems and personnel of their impending activation.

Standby: Initiate decision-making processes for imminent activation, including mobilization of resources and personnel.

Activate: Implementation of the community mitigation strategy.

*Widespread human outbreaks in multiple locations overseas.

†First human case in North America.

§Spread throughout the United States.

¶Recommendations for regional planning acknowledge the tight linkages that

may exist between cities and metropolitan areas that are not encompassed within state boundaries.

**Standby applies. However, Alert actions for Category 4 and 5 should occur during WHO Phase 5, which corresponds to U.S. Government Stage 2.

††Standby/Activate Standby applies unless the laboratory-confirmed case cluster and community transmission occurs within a given jurisdiction, in which case that jurisdiction should proceed directly to Activate community interventions defined in Table 2.

cluster with evidence of community transmission is identified. The recommendation for that State or region is to *Activate* the appropriate NPIs as defined in Table 2 when identification of a cluster and community transmission is made. Other States or regions *Activate* appropriate interventions when they identify laboratory-confirmed human pandemic influenza case clusters with evidence of community transmission in their jurisdictions.

For Category 1, 2, and 3 pandemics, *Alert* is declared during U.S. Government Stage 3, with step-wise progression by States and regions to *Standby* based on U.S. Government declaration of Stage 4 and the identification of the first human pandemic influenza case(s) in the United States (Stage 5). Progression to *Activate* by a given State or region occurs when that State or region identifies a laboratory-confirmed human pandemic influenza case cluster with evidence of community transmission.

Determining the likely time frames for progression through *Alert*, *Standby*, and *Activate* postures is difficult. Predicting this progression would involve knowing 1) the speed at which the pandemic is progressing and 2) the segments of the population most likely to have severe illness. These two factors are dependent on a complex interaction of multiple factors, including but not limited to the novelty of the virus, efficiency of transmission, seasonal effects, and the use of countermeasures. Thus it is not possible to use these two factors to forecast progression prior to recognition and characterization of a pandemic outbreak, and predictions within the context of an initial outbreak investigation are subject to significant limitations. Therefore, from a pre-pandemic planning perspective and given the potential for exponential spread of pandemic disease, it is prudent to plan for a process of rapid implementation of the recommended measures.

Once the pandemic strain is established in the United States, it may not be necessary for States to wait for documented pandemic strain infections in their jurisdictions to guide their implementation of interventions, especially for a strain that is associated

with a high case fatality ratio or excess mortality rate. When a pandemic has demonstrated spread to several regions within the United States, less direct measures of influenza circulation (e.g., increases in influenza-like illness, hospitalization rates, or other locally available data demonstrating an increase above expected rates of respiratory illness) may be used to trigger implementation; however, such indirect measures may play a more prominent role in pandemics within the lower Pandemic Severity Index categories.

Once WHO has declared that the world has entered Pandemic Phase 5 (substantial pandemic risk), CDC will frequently provide guidance on the Pandemic Severity Index. These assessments of pandemic severity will be based on the most recent data available, whether obtained from the United States or from other countries, and may use case fatality ratio data, excess mortality data, or other data, whether available from outbreak investigations or from existing surveillance.

Duration of Implementation of Nonpharmaceutical Interventions

Preliminary analysis of historical data from selected U.S. cities during the 1918 pandemic suggests that duration of implementation is significantly associated with overall mortality rates. Stopping or limiting the intensity of interventions while pandemic virus was still circulating within the community was temporally associated with recrudescence increases in mortality due to pneumonia and influenza in some communities.^{20, 81} Total duration of implementation for the measures specified in this guidance will depend on the severity of the pandemic and the total duration of the pandemic wave in the community, which may average about 6-8 weeks in individual communities. However, because early implementation of pandemic mitigation interventions may reduce the virus's basic reproductive number, a *mitigated* pandemic wave may have lower amplitude but longer wavelength than an unmitigated pandemic wave (see Figure 2). Communities should therefore be prepared to maintain these measures for up to 12 weeks in a Category 4 or 5 pandemic.

It is important to emphasize that as long as susceptible individuals are present in large numbers, spread may continue. Immunity to infection with a pandemic strain can only occur after natural infection or immunization with an effective vaccine. The significant determinants for movement of a pandemic wave through a community are immunity and herd effect, and there is likely to be a residual pool of susceptible individuals in the community at all times. Thus, while NPIs may limit or slow community transmission, persisting pandemic virus circulating in a community with a susceptible population is a risk factor for re-emergence of the pandemic. Monitoring of excess mortality, case fatality ratios, or other surrogate markers over time will be important for determining both the optimal duration of implementation and the need for resumption of these

measures.

While the decisions to stop or limit the intensity of implementation are crucial factors in pandemic response, this document is primarily oriented to providing pre-pandemic planning guidance. It is recommended for planning purposes that a total duration of 12 weeks for implementation of these measures be considered, particularly with regard to severe pandemics of Category 4 or 5 in which recrudescence disease may have significant impact. However, for less severe pandemics, a shorter period of implementation may be adequate to achieving public health benefit.

This guidance recommends a three-tiered strategy for planning with respect to the duration of dismissal of children from schools, colleges and universities, and childcare programs (Table 2):

- No dismissal of students from schools or closure of childcare facilities in a Category 1 pandemic
- Short-term (up to 4 weeks) dismissal of students and closure of childcare facilities during a Category 2 or Category 3 pandemic
- Prolonged (up to 12 weeks) dismissal of students and closure of childcare facilities during a severe influenza pandemic (Category 4 or Category 5 pandemic)

This planning recommendation acknowledges the uncertainty around the length of time a pandemic virus will circulate in a given community and around the potential for recrudescence disease when use of NPIs is limited or stopped. When dismissals and closures are indicated for the most severe pandemics, thoughtful pre-planning for their prolonged duration may allow continued use of this intervention.

Critical Issues for the Use of Nonpharmaceutical Interventions

A number of outstanding issues should be addressed to optimize the planning for use of these measures. These issues include the establishment of sensitive and timely surveillance, the planning and conducting of multi-level exercises to evaluate the feasibility of implementation, and the identification and establishment of appropriate monitoring and evaluation systems. Policy guidance in development regarding the use of antiviral medications for prophylaxis, community and workplace-specific use of personal protective equipment, and safe home management of ill persons must be fast-tracked and prioritized as part of future versions of the overall community mitigation strategy. As well, developing appropriate and effective risk communication content and a means for its effective delivery, soliciting active community support and involvement in strategic planning decisions, and assisting individuals and families in identifying their own preparedness needs are critical community factors in achieving success.

Establishing and maintaining sensitive and timely surveillance at national, State, and local levels is critical. Achieving this goal will require enhancing the capability of local physicians and public health authorities to rapidly identify suspect cases of pandemic influenza. This increased capability may be facilitated by the development of point-of-care testing and the appropriate laboratory capacity and ability to transmit specimens and data to reference laboratories.

In addition, establishing protocols for notification of Federal authorities and establishing effective reporting and feedback systems to ensure information is shared appropriately to State and local decision-makers is a key requirement. Within this framework, focused support of established systems, such as the

121 Cities Mortality Reporting System⁸⁸, and the establishment of electronic mortality records may facilitate the rapid robust reporting of data elements to support the timely and appropriate implementation of NPIs. Similarly, establishing surveillance systems to monitor trends in disease in a community and to provide guidance on adjusting implementation of interventions and determining appropriate durations for intervention are critical components for implementation and will provide valuable data for decision-making around lifting interventions.

Critical issues remain with regard to ensuring both timely implementation and appropriate layering of interventions. Preliminary analysis of historical data and mathematical modeling suggest that the early, coordinated application of multiple interventions may be more effective in reducing transmission than the use of a single intervention. Multi-level exercises to evaluate the feasibility of implementation and identify critical enablers for use of these measures are required. In addition, early planning for appropriate monitoring and evaluation systems to provide assessment of the effectiveness of all proposed pandemic influenza interventions is needed. Policies and plans are required to ensure the availability of rapid diagnostic testing to distinguish influenza-like illness due to seasonal influenza strains and other respiratory pathogens from illnesses due to pandemic influenza strains. Accurate ascertainment of pandemic influenza cases is needed early during the course of a pandemic to minimize unnecessary application of mitigation interventions and in later stages of the pandemic to ascertain persisting community transmission.

Policies and planning for distribution of antiviral medications for treatment (and prophylaxis) needs to account for local capabilities, availability of the antiviral medications, and systems for distribution that could leverage the combined capabilities of public health organizations, the private sector, community organizations, and local governments. As well, guidance for community- and workplace-specific use of personal protective equipment is required, as are policies and planning to support their use.

Clear and consistent guidance is required for planning for home care of ill individuals, such as when and where to seek medical care, how to safely care for an ill individual at home, and how to minimize disease transmission in the household. In addition, guidance is required for appropriate use of community resources, such as home healthcare services, telephone care, the 9-1-1 emergency telephone system, emergency medical services, and triage services (nurse-advice lines, self-care guidance, and at-home monitoring systems) that could be deployed to provide resources for home care.

Community engagement is another critical issue for successful implementation and includes building a foundation of community preparedness to ensure compliance with pandemic mitigation measures. Community planners should use media and trusted sources in communities to 1) explain the concepts of pandemic preparedness, 2) explain what individuals and families can do to be better prepared, and 3) disseminate clear information about what the public may be asked to do in the case of a pandemic. In addition, developing and delivering effective risk communications in advance of and during a pandemic to guide the public in following official recommendations and to minimize fear and panic will be crucial to maintaining public trust.

Assessment of the Public on Feasibility of Implementation and Adherence

A Harvard School of Public Health public opinion poll was conducted with a nationally representative sample of adults over the age of 18 years in the United States in September-October 2006 to explore the public's willingness to adhere to community mitigation strategies. A majority of the almost 1,700 respondents reported their willingness to follow public health recommendations for the use of NPIs, but this poll also uncovered serious financial and other concerns.⁸⁹ The respondents were first read a scenario about an outbreak of pandemic influenza that spreads rapidly among humans and causes severe illness. They were then asked how they would respond to and be affected by the circumstances that would arise from such an outbreak.⁹⁰

Recognizing that their lives would be disrupted, most participants expressed willingness to limit contact with others at the workplace and in public places. More than three-fourths of respondents said they would cooperate if public health officials recommended that for 1 month they curtail various activities of their daily lives, such as using public transportation, going to the mall, and going to church/religious services. However, the poll respondents were not asked if they would be willing to follow those recommendations for longer periods in the case of a severe pandemic.

More than nine in ten (94 percent) said they would stay at home away from other people for 7-10 days if they had pandemic influenza. Nearly three-fourths (73 percent) said they would have someone to take care of them at home if they became ill with pandemic influenza and had to remain at home for seven to ten days. However, about one in four (24 percent) said they would not have someone to take care of them.

In addition, 85 percent of the respondents said they and all members of their household would stay at home for seven to ten days if another member of their household was ill. However, about three-fourths (76 percent) said they would be worried that if they stayed at home with a household member who was ill from pandemic influenza, they themselves would become ill from the disease. A substantial proportion of the public believed that they or a household member would be likely to experience various problems, such as losing pay, being unable to get the healthcare or prescription drugs they need, or being unable to get care for an older or disabled person, if they stayed at home for 7-10 days and avoided contact with anyone outside their household.

If schools and daycare were closed for 1 month, 93 percent of adults who have major responsibility for children under age 5 who are normally in daycare or for children 5 to 17 years of age and who have at least one employed adult in the household think they would be able to arrange care so that at least one employed adult in the household could go to work. Almost as many (86 percent) believe they would be able to do so if schools were closed for 3 months.

When asked about possible financial difficulties due to missed work, a greater number of respondents reported they would face financial problems. While most employed people (74 percent) believed they could miss 7-10 days of work without having serious financial problems, one in four (25 percent) said they would face such problems. A majority (57 percent) think they would have serious financial problems if they had to miss work for 1 month, and three-fourths of respondents (76 percent) thought they would have such problems if they were away from work for 3 months.

The Public Engagement Project on Community Control Measures against a Severe Pandemic of Influenza was carried out in October and November 2006.⁹¹ Two to three representatives from the organized stakeholder public were chosen from approximately ten major sectors likely to be affected by the measures (e.g., public health, education, private sector) to form a 50-member national level panel. In addition, a representative sample of approximately 260 citizens from the general public was recruited from Seattle, Washington; Syracuse, New York; Lincoln, Nebraska; and Atlanta, Georgia. Participants were presented with a scenario describing a severe pandemic and asked to consider their support for the use of the NPIs outlined above.

Approximately 95 percent or more of the citizens and stakeholders supported encouraging ill persons to stay at home, and the same high percentage supported canceling large public gatherings and altering work patterns for the purpose of social distancing. A lower percentage (83-84 percent) supported encouraging the members of households with ill persons to stay at home, and a similar percentage favored closing schools and large day care facilities for an extended period. Overall, approximately two-thirds of both citizens and stakeholders (64-70 percent) supported all of the interventions. Based on the scenario of a severe pandemic, nearly half (44-48 percent) of the citizens and stakeholders supported implementation of the interventions when pandemic influenza first strikes the United States, and approximately one-third of the public supported implementation when influenza first strikes in their State.

Although the findings from this poll and public engagement activity reported high levels of willingness to follow pandemic mitigation recommendations, it is uncertain how the public might react when a pandemic occurs. These results need to be interpreted with caution in advance of a severe pandemic that could cause prolonged disruption of daily life and widespread illness in a community. Adherence rates may be higher during the early stages of a pandemic and adherence fatigue may increase in the later stages. These results may

not be able to predict how the public would respond to a severe pandemic in their community nor predict how the public will tolerate measures that must be sustained for several months. Changes in perceived risk from observed mortality and morbidity during a pandemic relative to the need for income and the level of community and individual/family disruption caused by the mitigation interventions may be major determinants of changes in public adherence.

Planning to Minimize Consequences of Community Mitigation Strategy

Pandemic mitigation interventions will pose challenges for individuals and families, employers (both public and private), and local communities. Some cascading second- and third-order effects will arise as a consequence of the use of NPIs. However, until a pandemic-strain vaccine is widely available during a pandemic, these interventions are key measures to reduce disease transmission and protect the health of Americans. The community mitigation strategy emphasizes care in the home and underscores the need for individual, family, and employer preparedness. Adherence to these interventions will test the resiliency of individuals, families, and employers.

The major areas of concern derive from the recommendation to dismiss children from school and closure of childcare programs. The concerns include 1) the economic impact to families; 2) the potential disruption to all employers, including businesses and governmental agencies; 3) access to essential goods and services; and 4) the disruption of school-related services (e.g., school meal programs). Other interventions, such as home isolation and voluntary home quarantine of members of households with ill persons, would also contribute to increased absenteeism from work and affect both business operations and employees. These issues are of particular concern for vulnerable populations who may be disproportionately impacted.

However, these and other consequences may occur in the absence of community-wide interventions because of spontaneous action by the public or as a result of closures of schools and workplaces related to absenteeism of students and employees. These consequences associated with the pandemic mitigation interventions must be weighed against

the economic and social costs of an unmitigated pandemic.

Many families already employ a number of strategies to balance childcare and work responsibilities. Pandemic mitigation interventions, especially dismissal of students from school classes and childcare programs, will be even more challenging. These efforts will require the active planning and engagement of all sectors of society.

Impact of School Closure on the Workforce

Workplace absenteeism is the primary issue underlying many of the concerns related to the pandemic mitigation strategies. Absenteeism for child minding could last as long as 12 weeks for a severe pandemic. The potential loss of personal income or employment due to absenteeism related to prolonged cancellation of school classes and the need for child minding can lead to financial insecurity, fear, and worry. Workplace absenteeism, if severe enough, could also affect employers and contribute to some workplaces reducing or closing operations (either temporarily or permanently). Depending on the employers affected, this could limit the availability of essential goods and services provided by the private sector and the government, interrupting critical business supply chains and potentially threatening the ability to sustain critical infrastructure. Workplace absenteeism and the resulting interruption of household income would test the resiliency of all families and individuals but would be particularly challenging for vulnerable populations. The potential impact on society underscores the need for preparedness of individuals, families, businesses, organizations, government agencies, and communities.

There are 300 million Americans living in 116 million households in the United States.⁹² Approximately one-third of U.S. households (40 million) include children less than 18 years of age. In slightly more than half of these households (22 million), all adults present are working. Five million of these households have only a single working adult present. These households with children and only one working adult would be impacted disproportionately—potentially requiring the single working adult in the household to remain home to mind the children if students were dismissed from schools or childcare facilities were closed.

Depending upon the age threshold assumed for children requiring adult supervision, the impact of dismissing students from school and closure of childcare programs on working families would vary. The number of households impacted could range from 12.4 million (assuming children <13 years of age would require adult supervision) to 15.4 million (assuming children <15 years of age would require full-time adult supervision).

The projected impact of these estimates, however, does not fully account for the strategies families already employ to care for their children and remain in the workforce. Families with all adults in the household working currently utilize a number of strategies for child minding, including the assistance of other family members, such as grandparents and siblings, assistance from separated/divorced spouses, children minding themselves, staggered work/child-minding shifts for parents, and parents working from home. There are 60 million children under the age of 15. Over half these children (32 million or 56 percent) have a working mother. Nearly one-third (29 percent) of these children have a mother who works a non-day shift. Nearly one-third (29 percent) have a mother working part time. Nearly one-third (30 percent) of children under age 5 living with only their father in the household were regularly cared for by their mother while their father was working or in school. One of seven (14 percent) school age children, 5-14 years of age, living with only one parent in the household were regularly cared for by

the other parent while their father or mother was working or attending school.⁹³

The Harvard School of Public Health public opinion poll reported that 86 percent of families with children under age 5 in childcare or children 5-17 years of age would be able to arrange for childcare to allow at least one adult in the household to continue to work if classes and childcare were cancelled for 3 months.⁸⁹ These findings, when applied to the overall population, suggest that approximately one in seven households with children attending school or childcare would be unable to have at least one adult continue to work during a prolonged period of school and childcare cancellation.

Impact of Voluntary Home Isolation and Voluntary Home Quarantine

The impacts of pandemic mitigation interventions on workplace absenteeism are overlapping. In contrast to possible prolonged absenteeism for child minding, voluntary home quarantine would require all household members of an ill individual to remain home for approximately 1 week (single-person households, representing 27 percent of all U.S. households, would not be impacted by this intervention). In addition, ill individuals would stay home from work for a period of approximately 7-10 days. When estimating overall absenteeism, this hierarchy suggests first considering the impact of child minding, then illness, then quarantine. For example, if a working single parent remains home from work for 12 weeks to mind her children, workplace absenteeism is unaffected if one of her children becomes ill and the home voluntarily quarantines itself (the adult will remain absent from the workplace for 12 weeks due to child minding). If a working adult living in a household of two or more people becomes ill and is absent due to illness, the additional impact of absenteeism related to voluntary home quarantine would only apply if there are other non-ill working adults present in the household.

Absenteeism due to illness is directly related to the rate of clinical illness in the population. The proposed community interventions attempt to reduce

disease transmission and illness rates. As illness rates are reduced, absenteeism related to illness and quarantine would be expected to decline, whereas absenteeism related to child minding would remain constant.

The feasibility of following pandemic mitigation interventions is of particular concern for vulnerable populations (e.g., people who are living alone, the poor or working poor, elderly, [particularly those who are homebound], homeless, recent immigrants, disabled, institutionalized, or incarcerated). More than 31 million individuals in the United States live alone (27 percent of all households) and one-third of these individuals are age 65 years or older. According to the Harvard School of Public Health public opinion poll, 45 percent of respondents living in one-adult households report they would not have anyone to take care of them in the event of a pandemic.⁹⁰ More than four in ten respondents living in one-adult households (45 percent) and about one-third of low-income (36 percent), African-American (34 percent), disabled (33 percent), or chronically ill (32 percent) adults said they would not have anyone to take care of them if they were ill and had to remain at home. Similarly among people age 65 or over, those who live in one-adult households were far more likely (41 percent vs 15 percent) than those who lived in two-adult households with another person age 65 or over to say they would have no one to take care of them.

Additionally, the millions of frail elderly individuals who require life-sustaining supports to remain in the community would need additional consideration. Planning should begin now to include solutions to address the needs of the frail elderly. Of the approximately 45 million seniors (age 65 years and older) currently in the United States, 5 percent, or 2.25 million are considered frail. Currently the Elderly Nutrition Program provides meals for approximately 3 million elderly participants, including the frail elderly, in congregate settings, or through volunteers who provide homebound seniors with home-delivered meals. Participants receive approximately half of their daily nutritional needs from those meals. In addition, other related

community-based services, such as transportation and healthcare, are critical for seniors, particularly the frail elderly, who receive this assistance in order to maintain their independence.^{94,95} Communities will need to plan for how these vital supports can continue both for this population as well as for other groups with unique physical and mental challenges in light of efforts to protect lives and limit the spread of disease.

Strategies to Minimize Impact of Workplace Absenteeism

Solutions or strategies for minimizing the impact of dismissal of students from school and closure of childcare programs and workplace absenteeism may include the following: 1) employing child-minding strategies to permit continued employment; 2) employing flexible work arrangements to allow persons who are minding children or in quarantine to continue to work; 3) minimizing the impact on household income through income replacement; and 4) ensuring job security.

In contrast to the unpredictable nature of workplace absenteeism related to illness (unpredictability of who will be affected and who will be absent from work), it may be easier to forecast who is likely to be impacted by the dismissal of students from school and/or the closure of childcare. Accordingly, early planning and preparedness by employers, communities, individuals, and families is critical to minimizing the impact of this intervention on families and businesses.

In a severe pandemic, parents would be advised to protect their children by reducing out-of-school social contacts and mixing with other children.⁹⁶ The safest arrangement would be to limit contact to immediate family members and for those family members to care for children in the home. However, if this is not feasible, families may be able to develop support systems with co-workers, friends, families, or neighbors, to meet ongoing childcare needs. For example, they could prepare a plan in which two to three families work together to supervise and provide care for a small group of infants and young children. As was noted in the Harvard School of Public Health public opinion poll, parents reported that they would

primarily depend upon family members to assist with child minding (self/family member in the home, 82 percent; children caring for themselves, 6 percent; family member outside the home, 5 percent; and combination, 5 percent). One of four households with children under age 5 in childcare or children 5-17 years of age estimated that they would be able to work from home and care for their children. Students returning home from colleges and universities may also be available to assist with child minding.⁹⁰

More than half (57 percent) of private-sector employees have access to paid sick leave.⁹⁷ More than three-fourths (77 percent) have paid vacation leave, and 37 percent have paid personal leave. Currently, leave policies would likely not cover the extended time associated with child minding. Expanded leave policies and use of workplace flexibilities, including staggered shifts and telework, would help employees balance their work and family responsibilities during a severe pandemic. Additional options to offset the income loss for some employees meeting specific requirements include provisions for Unemployment Insurance. In addition, following a “major disaster” declaration under the Stafford Act, additional individual assistance, including Disaster Unemployment Assistance, may become available to eligible persons. The Family and Medical Leave Act may also offer protections in terms of job security for up to 12 weeks for covered and eligible employees who have a serious health condition or who are caring for a family member with a serious health condition.

In addition to employers expanding leave policies and adopting workplace flexibilities, Federal, State, local, tribal, and territorial officials should review laws, regulations, and policies to identify ways to help mitigate the economic impact of a severe pandemic and implementation of the pandemic mitigation measures on employers, individuals, and families, especially vulnerable populations. Clarity on such policies from employers and the government will help workers plan and prepare for the potential threat of a severe pandemic and to plan and comply with the pandemic mitigation intervention. Many of these programs and policies would also be applicable if

no pandemic mitigation measures were in place and absences were due to personal illness or the need to care for an ill family member.

Interruption of School Meal Programs

An additional concern related to dismissal of students is the interruption of services provided by schools, including nutritional assistance through the school meal programs. This would alter the nature of services schools provide and require that essential support services, including nutritional assistance to vulnerable children, be sustained through alternative arrangements.

The National School Lunch Program operates in more than 100,000 public and non-profit private schools and residential childcare institutions⁹⁸, and the School Breakfast Program operates in approximately 80,000 schools⁹⁹. School lunch and breakfast are free for students at or below 130 percent of the poverty level and are available at reduced price for students between 130 percent and 185 percent poverty level. Half of the thirty million students that participate in the School Lunch Program received free meals in 2006. During the summer, a Summer Food Service Program operates at more than 30,000 sites, providing breakfast, lunch and snacks to children living in low-income areas; the program served approximately 1.9 million total students in 2005.¹⁰⁰

According to the Harvard School of Public Health public opinion poll, 13 percent of households with children receiving free school meals reported that they would have a major problem if schools were closed and meals discontinued.⁹⁰ Approximately 15 million children currently receive free school meals; thus, it is anticipated that about 2 million would have a major problem associated with the interruption of school meals.

Many of these households also depend upon other Federal nutrition programs, including the Food Stamp Program, the Special Supplemental Nutrition Program for Women, Infants, and Children, and the Child and Adult Care Food Program, and community food pantries.

Strategies to Minimize the Impact of Interrupting School Meals

During a severe pandemic, it will be important for individuals and families to plan to have extra supplies on hand, as people may not be able to get to a store, stores may be out of supplies, and other services (e.g., community soup kitchens and food pantries) may be disrupted. Communities and families with school-age children who rely on school meal programs should anticipate and plan as best they can for a disruption of these services and school meal programs for up to 12 weeks.

This may be particularly challenging for families with children who already depend on a number of these programs. The Federal Government is working together with State and local emergency response planners to find creative solutions to meet nutrition assistance needs for vulnerable populations. Local government and faith-based and community leaders are being encouraged to work closely with nutrition program administrators at the local, State, and Federal level to:

- Develop plans to address community nutrition assistance needs during a pandemic
- Identify nutrition program adaptations needed to respond to social distancing, voluntary quarantines, and possible disruption of the normal food supply
- Address challenges related to the supply and delivery of food through commercial markets
- Identify current program flexibilities/authorities and determine if others are needed

School Resources Available for Community Service

If students are dismissed from school but schools remain open, school- and education-related assets, including school buildings, school kitchens, school buses, and staff, may continue to remain operational and potentially be of value to the community in many other ways. In addition, faculty and staff may be able to continue to provide lessons and other services to students by television, radio, mail, Internet, telephone, or other media. Continued instruction is not only

important for maintaining learning but also serves as a strategy to engage students in a constructive activity during the time that they are being asked to remain at home.

Impact on Americans Living Abroad

Although this document primarily considers a domestic influenza pandemic, it provides guidance that is relevant to American organizations and individuals based abroad. There are approximately 7 million American citizens living overseas. About 3 million of these are working abroad on behalf of more than 50 Federal agencies, although the vast majority are employees of the U.S. Department of Defense and their dependents.^{101, 102} In addition, there are 194 American Overseas Schools that have students in all grades, the vast majority of whom are children of U.S. citizens working in government or for private companies and contractors. Excluding the military, approximately one-third of American households overseas have children under 18 years of age, and approximately half are households in which both parents work.¹⁰³ (“American households” in this context is defined as households in which the head of household is a U.S. citizen without dual citizenship.) The impact of pandemic mitigation measures on Americans overseas would be similar to that in the United States, except that there are very few extended family members overseas to assist in childcare should schools be closed. As a result, a decision to dismiss students from school and close childcare could result in increased workplace absenteeism. This might be partially offset by the fact that single-parent households with children are less common among Americans abroad than in the United States.

During a pandemic, security for Americans abroad could become an increased concern, particularly in those countries that are unstable or lack the capability to prevent lawlessness. In such instances, the desire to close institutions, such as schools or embassies, must be balanced against the greater protection that can be provided to American citizens who are gathered in one place, rather than distributed in their homes. Additionally, an estimated one-third (80 of 250) of U.S. diplomatic posts abroad have

undependable infrastructure for water, electricity, and food availability, which may impair the ability of people to adhere to NPIs.¹⁰³

In consideration of these factors, many Americans may wish to repatriate to the United States at the outset of a pandemic, and this should be considered in decisions to implement closure of institutions and other NPIs in the international setting.

Strategy to Reduce Impact on Americans Living Abroad

Americans abroad should review pandemic preparedness recommendations issued by the U.S. Department of State and the U.S. Department of Health and Human Services. Updated regional and country-specific information is provided on www.pandemicflu.gov, the CDC travel website (www.cdc.gov/travel/), and the U.S. Department of State's travel site (www.travel.state.gov). In addition, two million of the estimated 4.5 million non-military affiliated Americans abroad are registered with U.S. Embassies and Consulates, and are thus able to receive warnings and announcements from these diplomatic posts. Those preparing to travel overseas can register for country-specific announcements online <https://travelregistration.State.gov/ibrs/>.

Americans should not assume that international transportation would be available during a pandemic. As a result, Americans abroad should identify local sources of healthcare and prepare to “shelter-in-place” if necessary. In those areas with potentially limited water and food availability, Americans living abroad are encouraged to maintain supplies of food and water to last at least two and as long as 12 weeks. Additional recommendations for preparing for a pandemic while abroad are available in the State Department fact sheet *How to Prepare for “Sheltering-In-Place,”* which is available at http://travel.State.gov/travel/tips/health/health_3096.html.

Testing and Exercising Community Mitigation Interventions

Because pandemics occur rarely, drills and exercises are required to test plans and to maintain response proficiency. Such real-world operational experience could yield invaluable empirical evidence regarding how readily particular pandemic mitigation measures might be implemented and how well they might work if applied on a larger scale and/or for longer duration. Drills and exercises permit individuals and organizations to carry out their normal duties and relate to each other under unusual circumstances in simulated environments that are far less costly and threatening than real events.

Discussion-based exercises (e.g., tabletop exercises) are a first step to help identify “gaps” in the plans, policies, protocols, processes, and procedures, included in planning for pandemic mitigation interventions. Such gaps should be filled before expensive, resource-intensive, operations-based drills and exercises are conducted. For example, developing community communications plans to notify the public about the status of a pandemic, what protective actions should be taken, and where to seek medical advice during a pandemic, as well as planning for distribution of antiviral medications, determining the process for dismissal of students from schools and closure of childcare facilities, and planning for possible closure of mass gatherings should be decided before conducting a full-scale exercise.

As responders practice the plan through exercising, they learn which aspects of response do not “go as planned.” After the exercise, responders debrief (“hot wash”) and create an after-action-report to describe corrective actions to fix response problems, including who is responsible for fixing what by when (a

“corrective action plan”). Proposed solutions should be re-tested to ensure that they adequately correct the response problem.

In July 2006, CDC’s Coordinating Office of Terrorism Preparedness and Emergency Response provided supplemental guidance for recipients of Federal funding through the *Public Health Preparedness and Response Cooperative Agreement* (Cooperative Agreement AA154) specifically intended to foster developing and exercising pandemic influenza plans. Specific performance measures for testing and exercising plans are listed in that guidance, which can be accessed at <http://www.bt.cdc.gov/planning/coopagreement/pdf/phase2-panflu-guidance.pdf>.

Research Needs

A comprehensive research agenda for pandemic influenza is needed to improve the evidence base of the proposed NPIs described in this interim guidance. This agenda should include conducting studies to gain more knowledge of the epidemiology of influenza, the effectiveness of community-based interventions, the use of medical countermeasures that complement community interventions, the modification of existing mathematical modeling to include adverse societal consequences, and the development of new modeling frameworks to assess the effectiveness of interventions.^{6, 13, 14, 19, 20, 104-108} Research to clarify or expand upon these issues may be necessary during a pandemic outbreak. Thus, planning for accelerated Institutional Review Board approval in the setting of a pandemic may facilitate important research conducted in hospitals, public health departments, and universities.

Key areas for further research include the following:

- *Enhancing epidemiologic and laboratory surveillance systems for influenza:* Existing influenza surveillance systems have gaps in timeliness and completeness that will hamper adequate functioning during a pandemic. A high priority must be given to the development of more timely surveillance for laboratory-confirmed cases of human infections with novel influenza A viruses, methods to rapidly estimate the excess mortality rate during a pandemic, better use of existing electronic data sources, and the development of platforms that can be used to assess the effectiveness of pandemic interventions, including vaccines, antiviral medications, and NPIs.
- *Development of rapid diagnostics:* The development of sensitive and specific point-of-care rapid tests for influenza A subtypes with pandemic potential may play an important role in pandemic preparedness. Laboratory diagnosis of influenza is critical for treatment, prophylaxis, surveillance, vaccine development and efficacy, and the timing of the initiation of pandemic mitigation strategies.
- *Measurement of effectiveness of personal protective equipment (PPE, e.g., surgical masks and respirators) in community settings:* Quantification of the effectiveness of PPE for infection prevention, the ability of community members to correctly use PPE, the relative benefit of fit-testing for respirator-use in community settings, the utility of PPE for children and the elderly for whom PPE is not currently designed, and the relative contribution of PPE to safety in the context of other NPIs should be undertaken.
- *Determination of the trigger points for implementation of NPIs:* Infection with influenza results in annual community-based epidemics. While the historic data from 1918 on use of NPIs indicate an ecological relationship between timing and effectiveness, additional prospective data on timing of each of these measures will usefully complement the value of historic evidence. Studies of some of the NPIs can be conducted during sporadic outbreaks of seasonal influenza.
- *Determination of markers to signal that it might be appropriate to end or lift pandemic mitigation interventions:* Pandemic mitigation measures may be employed in communities until sufficient vaccine is available to that population or until other parameters are reached. Retrospective and other studies could provide detailed information

regarding these predictive factors.

- *Advancing the knowledge base on pharmaceutical interventions:* Antiviral medications and vaccines are integral components of pandemic mitigation strategies. Availability and use of medications can complement the effectiveness of voluntary isolation and quarantine and enhance compliance within communities. Therefore, the capacity to rapidly obtain data on antiviral and vaccine effectiveness, the development of resistance, and the assessment of distribution dynamics is important to successful implementation of pandemic mitigation strategies.
- *Determination, through prospective field studies, of the effectiveness of interventions required to achieve reduced transmission:* The evidence base for most of the interventions currently suggested for use is based on historic reviews, common sense, and biological plausibility. Evidence should be obtained through prospective trials or observational studies conducted during seasonal influenza outbreaks. Given the socioeconomic ramifications of pandemic mitigation interventions such as social distancing measures for children and adults, adherence with prolonged use of interventions is likely to be limited. Therefore, in addition to the assessment of effectiveness, studies should also be done to assess factors that promote compliance and the optimal duration of interventions.
- *Improved understanding of fundamental questions of influenza transmission and epidemiology:* Prospective epidemiological studies to address gaps in understanding of influenza epidemiology and transmission and the natural history of disease may guide the application of NPIs in the community.
- *Improved understanding of environmental factors that may influence influenza survival and transmissibility:* Studies to elucidate the impact of temperature, humidity, radiation, seasonality, and other factors and their relation to influenza transmission in communities are needed to identify complementary mitigation interventions.
- *Improved measures of uncertainty with regard to parameter and model estimates for mathematical modeling of NPIs:* Development of improved metrics of uncertainty around interpretation of modeling outputs may more appropriately guide the incorporation of modeling results into development of policy for community use of these measures.
- *Characterize and determine the potential psychosocial sequelae of voluntary home quarantine and social distancing strategies:* Investigation of the use of home quarantine and social distancing strategies in simulations and in severe seasonal influenza outbreaks could determine key issues that might arise during a severe pandemic requiring long-term social distancing strategies and might suggest possible strategies to reduce untoward effects. Studies that focus on incidences of school closure that might be used for other disease outbreaks might help to better understand facilitators and barriers to adherence with public health recommendations.
- *Expanded parameter inputs for modeling the potential effectiveness of school and workplace interventions in mitigating an influenza pandemic:* The current mathematical models have been prepared with a single option for each of the interventions. For example, the recommendation for dismissing students from schools is absolute and does not include options to partially implement this intervention. Given the societal consequences of this protective intervention, as well as other measures, it is recommended that models be further developed to study a broader range of options for each intervention.
- *Appropriate modeling of effect of interventions to limit the impact of cascading second- and third-order consequences of the use of NPIs:* The implementation challenges and cascading consequences of both the pandemic and of the interventions should be considered in the mathematical models. For example, broader outcome measures beyond influenza-related public health outcomes might include costs and benefits of intervention strategies.
- *Development of process indicators:* Given the need to assess community-level response capacity in any Incident of National Significance, a

research agenda related to mitigation of pandemic influenza should include development of tools to assess ongoing response capacity. These tools may include ways to assess adherence with interventions and to determine factors that influence adherence fatigue. Such tools would be most useful for the implementing jurisdictions in development of preparedness plans and for evaluating the implementation dynamics during a pandemic.

Conclusions

The goals of planning for an influenza pandemic are to save lives and to reduce adverse personal, social, and economic consequences of a pandemic; however, it is recognized that even the best plans may not completely protect everyone. Such planning must be done at the individual, local, tribal, State, Federal, and international levels, as well as by businesses and employers and other organizations, in a coordinated manner. Interventions intended for mitigating a pandemic pose challenges for individuals and families, employers (both public and private), schools, childcare programs, colleges and universities, and local communities. Pre-pandemic, scenario-based planning offers an opportunity to better understand and weigh the benefits of possible interventions as well as identify strategies to maximize the number of people protected while reducing, to the greatest extent possible, the adverse social, logistical, and economic effects of proposed interventions.

The early use of combinations of NPIs that are strategically targeted, layered, and implemented in a coordinated manner across neighboring jurisdictions and tailored to the severity of the pandemic is a critical component of a comprehensive strategy to reduce community disease transmission and mitigate illness and death. This guidance introduces, for the first time, a Pandemic Severity Index in which case fatality ratio serves as the critical driver for categorizing the severity of a pandemic. The severity index is designed to enable better forecasting of the impact of a pandemic and allows for fine-tuning the selection of the most appropriate tools and interventions, balancing the potential benefits against the expected costs and risks. Decision-makers may find the Pandemic Severity Index useful in a wide range of pandemic planning scenarios beyond

pandemic mitigation, including, for example, in plans for assessing the role for pre-pandemic vaccine or estimating medical ventilator supply and other healthcare surge requirements.

This planning guidance should be viewed as the first iteration of a dynamic process that will be revisited and refined on a regular basis and informed by new knowledge gained from research, exercises, and practical experience. The array of public health measures available for pandemic mitigation is also evolving, and future versions of this document will need to incorporate the changing landscape. Some critical priority issues for inclusion in subsequent drafts are highlighted in actions being pursued under the National Implementation Plan Action Items. These include the role and further development of point-of-care rapid influenza diagnostics, antiviral medications, pre-pandemic vaccines, face mask and respirator use in community settings, and home-care infection control management strategies. The development of sensitive and specific diagnostic tests for pandemic strains not only enables a more efficient use of antiviral medication for treatment and prophylaxis but also helps minimize the need for isolation and quarantine for persons with nonspecific respiratory infections. The increasing availability of antiviral medications will prompt new discussions about the role of antiviral prophylaxis for households and workers in critical infrastructure to further reduce transmission potential and to provide incentives to comply with voluntary home quarantine recommendations and for healthcare and other workers to report to work. Changes in the technology and availability of personal protective equipment will influence guidance on community use of face masks and respirators. Guidance for safe management of

ill family members in the household should serve to decrease the risk of household transmission of influenza, once again aligning incentives for compliance and increasing the effectiveness of pandemic mitigation interventions.

Planning and preparedness for implementing pandemic mitigation strategies is complex and requires participation by all levels of government and all segments of society. Pandemic mitigation strategies call for specific actions by individuals, families, businesses and employers, and organizations. Building a foundation of community and individual and family preparedness and developing and delivering effective risk communication for the public in advance of a pandemic is critical. If embraced earnestly, these efforts will result in enhanced ability to respond not only to pandemic influenza but also to multiple hazards and threats. While the challenge is formidable, the consequences of facing a severe pandemic unprepared will be intolerable. This interim pre-pandemic planning guidance is put forth as a step in our commitment to address the challenge of mitigating a pandemic by building and enhancing community resiliency.

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Appendices

Appendix 1 - Glossary of Terms

Absenteeism rate: Proportion of employed persons absent from work at a given point in time or over a defined period of time.

Antiviral medications: Medications presumed to be effective against potential pandemic influenza virus strains and which may prove useful for treatment of influenza-infected persons or for prophylactic treatment of persons exposed to influenza to prevent them from becoming ill. These antiviral medications include the neuraminidase inhibitors oseltamivir (Tamiflu®) and zanamivir (Relenza®).

Case fatality ratio: Proportion of deaths among clinically ill persons.

Childcare: Childcare programs discussed in this guidance include 1) centers or facilities that provide care to any number of children in a nonresidential setting, 2) large family childcare homes that provide care for seven or more children in the home of the provider, and 3) small family childcare homes that provide care to six or fewer children in the home of the provider.

Children: In this document children are defined as 17 years of age or younger unless an age is specified or 12 years of age or younger if teenagers are specified.

Clinically ill: Those persons who are infected with pandemic influenza and show signs and symptoms of illness.

Colleges: Post-high school educational institutions (i.e., beyond 12th grade).

Community mitigation strategy: A strategy for the implementation at the community level of interventions designed to slow or limit the transmission of a pandemic virus.

Cough etiquette: Covering the mouth and nose while coughing or sneezing; using tissues and disposing in no-touch receptacles; and washing of hands often to avoid spreading an infection to others.

Countermeasures: Refers to pre-pandemic and pandemic influenza vaccine and antiviral medications.

Critical infrastructure: Systems and assets, whether physical or virtual, so vital to the United States that the incapacitation or destruction of such systems and assets would have a debilitating impact on national security, economy, or public health and/or safety, either alone or in any combination. Specifically, it refers to the critical infrastructure sectors identified in Homeland Security Presidential Directive 7 (HSPD-7).

Early, targeted, and layered nonpharmaceutical interventions (NPIs) strategy: A strategy for using combinations of selected community-level NPIs implemented early and consistently to slow or limit community transmission of a pandemic virus.

Excess rate: Rate of an outcome (e.g., deaths, hospitalizations) during a pandemic above the rate that occurs normally in the absence of a pandemic. It may be calculated as a ratio over baseline or by subtracting the baseline rate from the total rate.

Face mask: Disposable surgical or procedure mask covering the nose and mouth of the wearer and designed to prevent the transmission of large respiratory droplets that may contain infectious material.

Faith-based organization: Any organization that has a faith-inspired interest.

Generation time: Average number of days taken for an ill person to transmit the infection to another person.

Hand hygiene: Hand washing with either plain soap or antimicrobial soap and water or use of alcohol-based products (gels, rinses, foams containing an emollient) that do not require the use of water.

Illness rate or clinical attack rate: Proportion of people in a community who develop illness (symptomatic cases ÷ population size).

Incident of National Significance: Designation is based on criteria established in Homeland Security Presidential Directive 5 and include events with actual or potential high-impact that requires a coordinated and effective response by Federal, State, local, tribal, nongovernmental, and/or private sector entities in order to save lives, minimize damage, and provide the basis for long-term community recovery and mitigation activities.

Incubation period: The interval (in hours, days, or weeks) between the initial, effective exposure to an infectious organism and the first appearance of symptoms of the infection.

Infection control: Hygiene and protective measures to reduce the risk of transmission of an infectious agent from an infected person to uninfected persons (e.g., hand hygiene, cough etiquette, use of personal protective equipment, such as face masks and respirators, and disinfection).

Influenza pandemic: A worldwide epidemic caused by the emergence of a new or novel influenza strain

to which humans have little or no immunity and which develops the ability to infect and be transmitted efficiently and sustainably between humans.

Isolation of ill people: Separation or restriction of movement of persons ill with an infectious disease in order to prevent transmission to others.

Mortality rate: Number of deaths in a community divided by population size of community over a specific period of time (e.g., 20 deaths per 100,000 persons per week).

Nonpharmaceutical intervention (NPI): Mitigation measure implemented to reduce the spread of an infectious disease (e.g., pandemic influenza) but one that does not include pharmaceutical products, such as vaccines and medicines. Examples include social distancing and infection control measures.

Pandemic vaccine: Vaccine for a specific influenza virus strain that has evolved the capacity for sustained and efficient human-to-human transmission. This vaccine can only be developed once the pandemic strain emerges.

Personal protective equipment (PPE): PPE is any type of clothing, equipment, or respiratory protection device (respirators) used to protect workers against hazards they encounter while doing their jobs. PPE can include protection for eyes, face, head, torso, and extremities. Gowns, face shields, gloves, face masks, and respirators are examples of PPE commonly used within healthcare facilities. When PPE is used in a workplace setting to protect workers against workplace hazards, its use must be consistent with regulations issued by the Occupational Safety and Health Administration (<http://www.osha.gov/index.html>).

Post-exposure prophylaxis: The use of antiviral medications in individuals exposed to others with influenza to prevent disease transmission.

Pre-pandemic vaccine: Vaccine against strains of influenza virus in animals that have caused isolated

infections in humans and which may have pandemic potential. This vaccine is prepared prior to the emergence of a pandemic strain and may be a good or poor match (and hence of greater or lesser protection) for the pandemic strain that ultimately emerges.

Prophylaxis: Prevention of disease or of a process that can lead to disease. With respect to pandemic influenza, this specifically refers to the administration of antiviral medications to healthy individuals for the prevention of influenza.

Quarantine: A restraint upon the activities or communication (e.g., physical separation or restriction of movement within the community/work setting) of an individual(s) who has been exposed to an infection but is not yet ill to prevent the spread of disease; quarantine may be applied voluntarily (preferred) or on compulsory basis dependent on legal authority.

Rapid diagnostic test: Medical test for rapidly confirming the presence of infection with a specific influenza strain.

Recrudescence: Reappearance of a disease after it has diminished or disappeared.

R_0 (“reproductive number”): Average number of infections resulting from a single case in a fully susceptible population without interventions. R_t : the reproductive number at a given time, t .

Schools: Refers to public and private elementary, middle, secondary, and post-secondary schools (colleges and universities).

Schools (K-12): Refers to schools, both public and private, spanning the grades kindergarten through 12th grade (elementary through high school).

Seasonal influenza: Influenza virus infections in familiar annual patterns.

Second- and third-order consequences: Chains of effects that may arise as a consequence of intervention

and which may require additional planning and intervention to mitigate. These terms generally refer to foreseeable unintended consequences of intervention. For example, dismissal of students from schools may lead to workplace absenteeism for child minding. Subsequent workplace closings due to high absenteeism may lead to loss of income for employees, a third-order effect that could be detrimental to families living at or near subsistence levels.

Sector: A subdivision (sociological, economic, or political) of society.

Social distancing: Measures to increase the space between people and decrease the frequency of contact among people.

Surge capacity: Refers to the ability to expand provision of services beyond normal capacity to meet transient increases in demand. Surge capacity within a medical context includes the ability of healthcare or laboratory facilities to provide care or services above their usual capacity and to expand manufacturing capacity of essential medical materiel (e.g., vaccine) to meet increased demand.

Surgical mask: Disposable face masks that covers the mouth and nose and comes in two basic types. The first type is affixed to the head with two ties and typically has a flexible adjustment for the nose bridge. This type of surgical mask may be flat/pleated or duck-billed in shape. The second type of surgical mask is pre-molded, or cup shaped, and adheres to the head with a single elastic strap and usually has a flexible adjustment for the nose bridge. Surgical masks are used to prevent the transmission of large particles.

Telework: Refers to activity of working away from the usual workplace (often at home) through telecommunication or other remote access means (e.g., computer, telephone, cellular phone, fax machine).

Universities: Educational institutions beyond 12th grade (post high school).

Viral shedding: Discharge of virus from an infected person.

Virulence: The ability of the pathogen to produce disease; or the factors associated with the pathogen to affect the severity of diseases in the host.

Voluntary: Acting or done of one's own free will without legal compulsion (e.g., voluntary household quarantine).

Appendix 2 – Interim Guidance Development Process

This guidance document was developed through a collaborative process that gathered input from a variety of sources, including subject-matter experts, peer-reviewed scientific literature, current research, and stakeholders (i.e., Federal agencies, public health officials, and the public). A working group composed of Federal, State, and local public health officials and representatives from the Association of State and Territorial Health Officials (ASTHO), the Council of State and Territorial Epidemiologists (CSTE), the National Association of County and City Health Officials (NACCHO), the Infectious Disease Society of America (IDSA), and the National Association of Local Boards of Health (NALBOH) met periodically to review and evaluate evidence derived from the following sources:

- Preliminary statistical analyses of historical data on the implementation of selected NPIs in U.S. cities during the 1918 pandemic.
- Stakeholder input from interagency outreach meetings with public health, private sector, labor unions, faith-based and community partners.
- Proceedings of community public engagement meetings conducted in five U.S. cities (Atlanta, GA; Lincoln, NE; Seattle, WA; Syracuse, NY; Washington, DC) in October-November 2006.
- Public opinion poll results conducted by the Harvard School of Public Health in September-October 2006 surveying 1,697 adults in the United States regarding their willingness to follow public health officials' recommendations for selected pandemic mitigation interventions.
- Peer-reviewed mathematical modeling to assess potential pandemic mitigation interventions during an influenza pandemic.
- Expert opinion of public health officials, including published findings and recommendations of the Committee on Modeling Community Containment for Pandemic Influenza (Institute of Medicine, 2006).
- Preliminary results from a November 2006 Epi-Aid investigation of a seasonal influenza outbreak with associated school closure.
- Preliminary results from review of legal authorities/policies of school closure in each state conducted by the Center for Law and the Public's Health.

In addition, stakeholders from government, academia, private industry, educational organizations, and faith-based and community organizations reviewed and evaluated these data during public stakeholder meetings in June and December 2006. The opinions from individuals in the working group and stakeholders were considered during the writing of this guidance.

Pandemic planning with respect to the implementation of these pandemic mitigation interventions must be citizen-centric and support the needs of people across society in as equitable a manner as possible. Accordingly, the process for developing this interim pre-pandemic guidance sought input from key stakeholders, including the public. While all views and perspectives were respected, a hierarchy of values did in fact emerge over the course of the deliberations. In all cases, the question was whether the cost of the interventions was commensurate with the benefits they could potentially provide. Thus, there was more agreement on what should be done when facing a severe pandemic with a high case fatality ratio (e.g., a 1918-like pandemic) than on what should be done

when facing a pandemic with a lower case fatality ratio (e.g., a 1968-like pandemic); even with the inherent uncertainties involved, the cost-benefit ratio of the interventions clearly becomes more favorable as the severity increases and the number of lives potentially saved increases. Many stakeholders, for example, expressed concern about the effectiveness of the proposed interventions, which cannot be demonstrated *a priori* and for which the evidence base is limited and of variable quality. However, where high rates of mortality could be anticipated in the absence of intervention, a significant majority of stakeholders expressed their willingness to “risk” undertaking interventions of uncertain effectiveness in mitigating disease and death. Where scenarios that

would result in 1918-like mortality rates were concerned, most stakeholders reported that aggressive measures would be warranted and that the value of the lives potentially saved assumed precedence over other considerations. However, the feasibility of these approaches has not been assessed at the community level. Local, State, regional, and Federal exercises will need to be conducted to obtain more information about the feasibility and acceptance of these measures. In addition, ongoing engagement with the public, especially vulnerable populations, is essential.

CDC Community Mitigation Strategy Team acknowledges the following for their contributions to the development of this document

| | |
|---|--|
| Department of Health and Human Services | Association of State and Territorial Health Officials |
| Department of Commerce | Council of State and Territorial Epidemiologists |
| Department of Defense | Harvard School of Public Health |
| Department of Education | Infectious Diseases Society of America |
| Department of Homeland Security | Institute of Medicine |
| Department of the Interior | National Association of County and City Health Officials |
| Department of Justice | National Association of Local Health Boards |
| Department of Labor | MIDAS Modelers |
| Department of State | University of Michigan |
| Department of Transportation | |
| Department of the Treasury | |
| United States Department of Agriculture | |
| United States Environmental Protection Agency | |
| United States Office of Personnel Management | |
| Department of Veterans Affairs | |
| White House Homeland Security Council | |

Appendix 3 - WHO Phases of a Pandemic/ U.S. Government Stages of a Pandemic

PANDEMIC INFLUENZA

WHO Global Pandemic Phases and the Stages for Federal Government Response

| WHO Phases | | Federal Government Response Stages | |
|------------------------------|---|------------------------------------|---|
| INTER-PANDEMIC PERIOD | | | |
| 1 | No new influenza virus subtypes have been detected in humans. An influenza virus subtype that has caused human infection may be present in animals. If present in animals, the risk of human disease is considered to be low. | 0 | New domestic animal outbreak in at-risk country |
| 2 | No new influenza virus subtypes have been detected in humans. However, a circulating animal influenza virus subtype poses a substantial risk of human disease. | | |
| PANDEMIC ALERT PERIOD | | | |
| 3 | Human infection(s) with a new subtype, but no human-to-human spread, or at most rare instances of spread to a close contact. | 0 | New domestic animal outbreak in at-risk country |
| | | 1 | Suspected human outbreak overseas |
| 4 | Small cluster(s) with limited human-to-human transmission but spread is highly localized, suggesting that the virus is not well adapted to humans. | 2 | Confirmed human outbreak overseas |
| 5 | Larger cluster(s) but human-to-human spread still localized, suggesting that the virus is becoming increasingly better adapted to humans, but may not yet be fully transmissible (substantial pandemic risk). | | |
| PANDEMIC PERIOD | | | |
| 6 | Pandemic phase: increased and sustained transmission in general population. | 3 | Widespread human outbreaks in multiple locations overseas |
| | | 4 | First human case in North America |
| | | 5 | Spread throughout United States |
| | | 6 | Recovery and preparation for subsequent waves |

Appendix 4 - Pandemic Influenza Community Mitigation Interim Planning Guide for Businesses and Other Employers

Purpose

This Interim Planning Guide for Businesses and Other Employers is provided as a supplement to the *Interim Pre-Pandemic Planning Guidance: Community Strategy for Pandemic Influenza Mitigation in the United States—Early, Targeted, Layered Use of Nonpharmaceutical Interventions*. This guide is intended to assist in pre-pandemic planning. Individuals and families, employers, schools, and other organizations will be asked to take certain steps (described below) to help limit the spread of a pandemic, mitigate disease and death, lessen the impact on the economy, and maintain societal functioning. This guidance is based upon the best available current data and will be updated as new information becomes available. During the planning process, Federal, State, local, tribal, and territorial officials should review the laws, regulations, and policies that relate to these recommendations, and they should include stakeholders in the planning process and resolution of issues.

Businesses and other employers (including local, State, and Federal agencies and other organizations) will be essential partners in protecting the public's health and safety when a pandemic occurs. This *Pandemic Influenza Community Mitigation Interim Planning Guide for Businesses and Other Employers* provides guidance to these groups by describing how they might prepare for, respond to, and recover from an influenza pandemic. When an influenza pandemic starts, public health officials will determine the severity of the pandemic and recommend actions to protect the community's health. People who become severely ill may need to be cared for in a hospital. However, most people with influenza will be safely cared for at home.

Community mitigation recommendations will be based on the severity of the pandemic and may include the following:

1. Asking ill people to voluntarily remain at home and not go to work or out in the community for about 7-10 days or until they are well and can no longer spread the infection to others (ill individuals may be treated with influenza antiviral medications, as appropriate, if these medications are effective and available).
2. Asking members of households with a person who is ill to voluntarily remain at home for about 7 days (household members may be provided with antiviral medications, if these medications are effective and sufficient in quantity and feasible mechanisms for their distribution have been developed).
3. Dismissing students from schools (including public and private schools as well as colleges and universities) and school-based activities and closure of childcare programs for up to 12 weeks, coupled with protecting children and teenagers through social distancing in the community, to include reductions of out-of-school social contacts and community mixing. Childcare programs discussed in this guidance include centers or facilities that provide care to any number of children in a nonresidential setting, large family childcare homes that provide care for seven or more children in the home of the provider, and small family childcare homes that provide care to six or fewer children in the home of the provider.¹
4. Recommending social distancing of adults in the community, which may include cancellation of large public gatherings; changing workplace environments and schedules to decrease social density and preserve

a healthy workplace to the greatest extent possible without disrupting essential services; ensuring work-leave policies to align incentives and facilitate adherence with the measures outlined above.

Planning now for a severe pandemic (and adjusting your continuity plan accordingly) will help assure that your business is prepared to implement these community recommendations. Businesses and other employers should be prepared to continue the provision of essential services during a pandemic even in the face of significant and sustained absenteeism. Pandemic preparation should include coordinated planning with employees and employee representatives and critical suppliers. Businesses should also integrate their planning into their communities' planning. These preparedness efforts will be beneficial to your organization, staff, and the community, regardless of the severity of the pandemic. The following provide information to guide business planning for a pandemic: *Business Pandemic Influenza Planning Checklist* (www.pandemicflu.gov/plan/business/businesschecklist.html), the *Pandemic Preparedness Planning for U.S. Businesses with Overseas Operations Checklist*, (<http://www.pandemicflu.gov/plan/business/businessesoverseas.pdf>), and the *Pandemic Influenza Preparedness, Response and Recovery Guide for Critical Infrastructure and Key Resources* (<http://www.pandemicflu.gov/plan/pdf/cikrpandemicinfluenzaguide.pdf>). In addition, recommendations for implementation of pandemic mitigation strategies are available at www.pandemicflu.gov. Reliable, accurate, and timely information on the status and severity of the pandemic also will be posted on www.pandemicflu.gov. Additional information is available from the Centers for Disease Control and Prevention (CDC) Hotline: 1-800-CDC-INFO (1-800-232-4636). This line is available in English and Spanish, 24 hours a day, 7 days a week. TTY: 1-888-232-6348. Questions can be e-mailed to cdcinfo@cdc.gov.

Recommendations for Planning

Plan for ill individuals to remain at home

- Plan for staff absences during a pandemic due to personal illness.
 - Encourage ill persons to stay home during a pandemic and establish return-to-work policies after illness.
 - Identify critical job functions and plan for their continuity and how to temporarily suspend non-critical activities, cross-train employees to cover critical functions, and cover the most critical functions with fewer staff.
 - Identify employees who might need extra assistance to stay home when they are ill because, for example, they live alone or are disabled.
 - Review Federal and State employment laws that identify your employer obligations and options for employees.
- Establish and clearly communicate policies on sick (and other) leave and employee compensation.
- Develop a workplace culture that recognizes and encourages behaviors such as voluntarily staying home when ill in order to get well and to avoid spreading infection to others.
- Develop policies on what to do when a person becomes ill at the workplace.
- Provide employees with information on taking care of ill people at home. Such information will be posted on www.pandemicflu.gov.

2. Plan for all household members of a person who is ill to voluntarily remain at home

- Plan for staff absences related to family member illness.
 - Identify critical job functions and plan for their continuity and how to temporarily suspend non-critical activities, cross-train employees to cover critical functions, and cover the most critical functions with fewer staff.
 - Establish policies for an alternate or flexible

worksite (e.g., work via the Internet, e-mailed or mailed work assignments) and flexible work hours, where feasible.

- Develop guidelines to address business continuity requirements created by jobs that will not allow teleworking (e.g., production or assembly line workers).
- Establish and clearly communicate policies on family leave and employee compensation, especially Federal laws and laws in your State regarding leave of workers who need to care for an ill family member or voluntarily remain home.
- Provide employees with information on taking care of ill people at home. Such information will be posted on www.pandemicflu.gov.

3. Plan for dismissal of students and childcare closure

- Identify employees who may need to stay home if schools dismiss students and childcare programs close during a severe pandemic.
- Advise employees not to bring their children to the workplace if childcare cannot be arranged.
- Plan for alternative staffing or staffing schedules on the basis of your identification of employees who may need to stay home.
 - Identify critical job functions and plan now for cross-training employees to cover those functions in case of prolonged absenteeism during a pandemic.
 - Establish policies for employees with children to work from home, if possible, and consider flexible work hours and schedules (e.g., staggered shifts).
- Encourage employees who have children in their household to make plans to care for their children if officials recommend dismissal of students from schools, colleges, universities, and childcare programs. Advise employees to plan for an extended period (up to 12 weeks) in case the pandemic is severe.
- In a severe pandemic, parents would be advised to protect their children by reducing out-of-school social contacts and mixing with other children. Although limiting all outside contact may not be feasible, parents may be able to develop support

systems with co-workers, friends, families, or neighbors if they continue to need childcare. For example, they could prepare a plan in which two to three families work together to supervise and provide care for a small group of infants and young children while their parents are at work (studies suggest that childcare group size of less than six children may be associated with fewer respiratory infections).²

- Talk with your employees about any benefits, programs, or other assistance they may be eligible for if they have to stay home to mind children for a prolonged period during a pandemic.
- Coordinate with State and local government and faith-based and community-based organizations to assist workers who cannot report to work for a prolonged period.

4. Plan for workplace and community social distancing measures

- Become familiar with social distancing methods that may be used during a pandemic to modify the frequency and type of person-to-person contact (e.g., reducing hand-shaking, limiting face-to-face meetings and shared workstations, promoting teleworking, offering liberal/unscheduled leave policies, staggered shifts).
- Plan to operate businesses and other workplaces using social distancing and other measures to minimize close contact between and among employees and customers. Determine how the work environment may be reconfigured to allow for more distance between employees and between employees and customers during a pandemic. If social distancing is not feasible in some work settings, employ other protective measures (guidance available at www.pandemicflu.gov).
- Review and implement guidance from the Occupational Safety and Health Administration (OSHA) to adopt appropriate work practices and precautions to protect employees from occupational exposure to influenza virus during a pandemic. Risk of occupational exposure to influenza virus depends in part on whether or not jobs require close proximity to people potentially

infected with the pandemic influenza virus or whether employees are required to have either repeated or extended contact with the public. OSHA will post and periodically update such guidance on www.pandemicflu.gov.

- Encourage good hygiene at the workplace. Provide employees and staff with information about the importance of hand hygiene (information can be found at <http://www.cdc.gov/cleanhands/>) as well as convenient access to soap and water and/or alcohol-based hand gel in your facility. Educate employees about covering their cough to prevent the spread of germs (<http://www.cdc.gov/flu/protect/covercough.htm>).

5. Communicate with your employees and staff

- Disseminate your company's pandemic plan to all employees and stakeholders in advance of a pandemic; include roles/actions expected of employees and other stakeholders during implementation of the plan.
- Provide information to encourage employees (and their families) to prepare for a pandemic by providing preparedness information. Resources are available at www.pandemicflu.gov/plan/individual/checklist.html.

6. Help your community

- Coordinate your business' pandemic plans and actions with local health and community planning.
- Find volunteers in your business who want to help people in need, such as elderly neighbors, single parents of small children, or people without the resources to get the medical or other help they will need.
- Think of ways your business can reach out to other businesses and others in your community to help them plan for a pandemic.
- Participate in community-wide exercises to enhance pandemic preparedness.

7. Recovery

- Assess criteria that need to be met to resume normal operations and provide notification

to employees of activation of the business resumption plan.

- Assess the availability of medical, mental health, and social services for employees after the pandemic.

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¹ American Academy of Pediatrics. Children in Out-of-Home Child Care: Classification of Care Service. In: Pickering LK, ed. Red Book: 2003 Report of the Committee on Infectious Diseases. 26th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2003:124.

² Bradley RH. Child care and common communicable illnesses in children aged 37 to 54 months. Arch Pediatr Adolesc Med. 2003 Feb;157(2):196-200

Appendix 5 - Pandemic Influenza Community Mitigation Interim Planning Guide for Childcare Programs

Purpose

This Interim Planning Guide for Childcare Programs is provided as a supplement to the *Interim Pre-Pandemic Planning Guidance: Community Strategy for Pandemic Influenza Mitigation in the United States—Early, Targeted, Layered Use of Nonpharmaceutical Interventions*. The guide is intended to assist in pre-pandemic planning. Individuals and families, employers, schools, and other organizations will be asked to take certain steps (described below) to help limit the spread of a pandemic, mitigate disease and death, lessen the impact on the economy, and maintain societal functioning. This guidance is based upon the best available current data and will be updated as new information becomes available. During the planning process, Federal, State, local, tribal, and territorial officials should review the laws, regulations, and policies that relate to these recommendations, and they should include stakeholders in the planning process and resolution of issues.

Childcare programs will be essential partners in protecting the public's health and safety when an influenza pandemic occurs. Childcare programs discussed in this guidance include centers or facilities that provide care to any number of children in a nonresidential setting, large family childcare homes that provide care for seven or more children in the home of the provider and small family childcare homes that provide care to six or fewer children in the home of the provider.¹ This *Pandemic Influenza Community Mitigation Interim Planning Guide for Childcare Programs* provides guidance describing how such programs might prepare for and respond to an influenza pandemic. When an influenza pandemic starts, public health officials will determine the

severity of the pandemic and recommend actions to protect the community's health. People who become severely ill may need to be cared for in a hospital. However, most people with influenza will be safely cared for at home.

Community mitigation recommendations will be based on the severity of the pandemic and may include the following:

1. Asking ill people to voluntarily remain at home and not go to work or out in the community for about 7-10 days or until they are well and can no longer spread the infection to others (ill individuals will be treated with influenza antiviral medications, as appropriate, if these medications are effective and available).
2. Asking members of households with a person who is ill to voluntarily remain at home for about 7 days (household members may be provided with antiviral medications, if these medications are effective and sufficient in quantity and feasible mechanisms for their distribution have been developed).
3. Dismissing students from schools (including public and private schools as well as colleges and universities) and school-based activities and closure of childcare programs for up to 12 weeks, coupled with protecting children and teenagers through social distancing in the community to include reductions of out-of-school social contacts and community mixing.
4. Recommending social distancing of adults in the community, which may include cancellation of large public gatherings; changing workplace environments and schedules to decrease social density and preserve a healthy workplace to the greatest extent possible without disrupting essential services; ensuring

work-leave policies to align incentives and facilitate adherence with the measures outlined above.

Recommendations for closing childcare facilities will depend upon the severity of the pandemic. The current three-tiered planning approach includes 1) no closure in a Category 1 pandemic, 2) short-term (up to 4 weeks) closure of childcare facilities in a Category 2 or Category 3 pandemic, and 3) prolonged (up to 12 weeks) closure of childcare facilities in a severe influenza pandemic (Category 4 or Category 5). These actions may only apply to traditional forms of center-based care and large family childcare programs (more than six children). Small family childcare programs (less than seven children) may be able to continue operations.

In the most severe pandemic, the duration of these public health measures would likely be for 12 weeks and will undoubtedly have serious financial implications for childcare workers and their employers as well as for families who depend on their services. In a severe pandemic, parents will be advised to protect their children by reducing out-of-school social contacts and mixing with other children. Although limiting all outside contact may not be feasible, families may be able to develop support systems with co-workers, friends, families, or neighbors if they continue to need childcare. For example, they could prepare a plan in which two or three families work together to supervise and provide care for a small group of infants and young children while their parents are at work (studies suggest that childcare group size of less than six children may be associated with fewer respiratory infections).²

Planning now for a severe pandemic will help assure that your childcare program is prepared to implement these community recommendations. These preparedness efforts will be beneficial to your programs, staff, families, and the community, regardless of the severity of the pandemic. The *Pandemic Flu Planning Checklist for Childcare Facilities* (<http://www.pandemicflu.gov/plan/school/index.html>) provides an approach to planning for a pandemic. Recommendations for implementation of

pandemic mitigation strategies are available at www.pandemicflu.gov. Reliable, accurate, and timely information on the status and severity of the pandemic will be posted on www.pandemicflu.gov. Additional information is available from the Centers for Disease Control and Prevention (CDC) Hotline: 1-800-CDC-INFO (1-800-232-4636). This line is available in English and Spanish, 24 hours a day, 7 days a week. TTY: 1-888-232-6348. Questions can be e-mailed to cdcinfo@cdc.gov.

Recommendations for Planning

1. Plan for ill individuals to remain at home

- Develop a plan of childcare operations for implementation during pandemics of all levels of severity.
- Develop a plan for employee absences due to personal illness. Plan for alternative staffing:
 - Identify critical job functions and plan for alternate coverage of those functions during a pandemic. Family childcare programs may consider prearranging childcare coverage with other providers in their areas.
 - Review and analyze Federal and State employment laws that identify employer obligations and options for personnel.
- Establish and clearly communicate policies on sick leave and employee compensation.
- Encourage ill persons to stay home during a pandemic and establish return-to-work policies after illness.
- Establish policies for sick-leave absences unique to a pandemic (e.g., liberal/unscheduled leave).
- Develop policies on observation for illness and what to do when a child or employee becomes ill at the workplace.
- Advise employees to look for information on taking care of ill people at home. Such information will be posted on www.pandemicflu.gov.

2. Plan for all household members of a person who is ill to voluntarily remain at home

- Develop a plan for employee absences related to

family member illness. Plan for alternate staffing:

- Identify critical job functions and plan now for coverage of those functions.
- Review Federal and State employment laws that identify your employer obligations and options for employees.
- Establish and clearly communicate policies on family leave and employee compensation.
- Establish policies for sick-leave absences unique to a pandemic (e.g., liberal/unscheduled leave).
- Establish policies for employees who have to stay home because someone in their household is ill with pandemic influenza.
- Be familiar with Federal and State laws regarding leave of workers who need to care for an ill family member or voluntarily remain at home.
- Advise employees to look for information on taking care of ill people at home. Such information will be posted on www.pandemicflu.gov.

3. Plan for dismissal of students from school and childcare closure, considering the impact on employees and parents

- Develop a plan for program operations during all levels of pandemic severity.
- Plan for alternate staffing based on your assessment.
 - Identify critical job functions and plan now for coverage of those functions in case of prolonged absenteeism during a pandemic.
- Work with State and local government and faith-based and community-based organizations to provide any needed assistance to staff who are not able to work for a prolonged period of time.

4. Plan for workplace and community social distancing measures

- Become familiar with social distancing actions that may be used during a pandemic to modify frequency and type of person-to-person contact (e.g., reducing hand-shaking, limiting face-to-face meetings, promoting teleworking, and offering liberal/unscheduled leave policies and staggered shifts).

- Plan to operate the workplace using social distancing and other measures to minimize close contact between employees.
 - Review and implement guidance from the Occupational Safety and Health Administration (OSHA) on appropriate work practices and precautions to protect employees from occupational exposure to influenza virus during a pandemic. Risks of occupational exposure to influenza virus depends in part on whether jobs require close proximity to people who may be infectious with the pandemic influenza virus or whether employees are required to have either repeated or extended contact with the general public. OSHA will post and periodically update such guidance on www.pandemicflu.gov.
 - If the childcare program is to remain in operation during a Category 1-3 pandemic, provide staff with information about the measures that the program will institute in order to reduce virus transmission among staff and children. These may include
 - Restructuring and keeping groups of staff and children from mixing together to minimize social contacts.
 - Asking ill staff to stay home while they are ill.
 - Modifying exclusion policies to include ill children and possibly, based on public health recommendations made at the time of the pandemic, those with ill family members.
 - Implementing staggered shifts.
 - Implementing social distancing practices, including
 - Eliminating gatherings of staff and
 - Minimizing contact between staff and parents
 - Encourage good hygiene at the workplace.
- Provide children and staff with information about the importance of hand hygiene (information can be found at <http://www.cdc.gov/cleanhands/>) as well as convenient access to soap and water and alcohol-based hand gel in your facility. Educate employees and children about covering their cough to prevent the spread of germs (see <http://www.cdc.gov/flu/protect/covercough.htm>).
- Promote social distancing of children outside the childcare setting by advising parents that children

reduce their social interaction and contacts to the greatest extent possible.

5. Communicate with staff and parents/families

- Be prepared to provide parents/families with information about
 - Why programs will be cancelled and the importance of keeping infants and children from congregating with other children in the community.
 - How alternative childcare options may be accessed.
 - How students who need free meals may qualify for other types of nutrition assistance in the community.
- Provide information to staff and parents/families on what they can do to prepare their families for a pandemic. Resources are available at <http://www.pandemicflu.gov/plan/individual/checklist.html> and www.ready.gov/america/index.html.
- Provide systematic emergency communications to childcare staff and families during the pandemic, using a telephone calling tree, an e-mail alert, or call-in voice recording to communicate pandemic status in the community and status of childcare program activities. Messages for staff and families should be targeted and provided in the different languages that reflect the languages within the community.
- Recommend that parents/families seek further information about pandemic through other sources including key Federal, State, local, tribal, and territorial public health resources and regularly provided pandemic updates at www.pandemicflu.gov.

6. Help your community

- Coordinate your pandemic plans and actions with local health and community planning.
- Think of ways your business can reach out to other businesses and others in your community to help them plan for a pandemic.
- Participate in community-wide exercises to enhance pandemic preparedness.

7. Recovery

- Establish the criteria and procedures for resuming childcare operations and activities.
- Develop communication plans for advising employees, staff, and families of the resumption of programs and activities.
- Develop the procedures, activities, and services needed to restore the childcare environment.

References:

¹ American Academy of Pediatrics. Children in Out-of-Home Child Care: Classification of Care Service. In: Pickering LK, ed. Red Book: 2003 Report of the Committee on Infectious Diseases. 26th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2003:124.

² Bradley RH. Child care and common communicable illnesses in children aged 37 to 54 months. Arch Pediatr Adolesc Med. 2003 Feb;157(2):196-200

Appendix 6 - Pandemic Influenza Community Mitigation Interim Planning Guide for Elementary and Secondary Schools

Purpose

This Interim Planning Guide for Elementary and Secondary Schools is provided as a supplement to the *Interim Pre-Pandemic Planning Guidance: Community Strategy for Pandemic Influenza Mitigation in the United States—Early, Targeted, Layered Use of Nonpharmaceutical Interventions*. The guide is intended to assist in pre-pandemic planning. Individuals and families, employers, schools, and other organizations will be asked to take certain steps (described below) to help limit the spread of a pandemic, mitigate disease and death, lessen the impact on the economy, and maintain societal functioning. This guidance is based upon the best available current data and will be updated as new information becomes available. During the planning process, Federal, State, local, tribal, and territorial officials should review the laws, regulations, and policies that relate to these recommendations, and they should include stakeholders in the planning process and resolution of issues.

Schools will be essential partners in protecting the public's health and safety when an influenza pandemic occurs. This *Pandemic Influenza Community Mitigation Interim Planning Guide for Elementary and Secondary Schools* provides guidance to educational institutions, describing how they might prepare for and respond to an influenza pandemic. When an influenza pandemic starts, public health officials will determine the severity of the pandemic and recommend actions to protect the community's health. People who become severely ill may need to be cared for in a hospital. However, most people with influenza will be safely cared for at home.

Community mitigation recommendations will be based on the severity of the pandemic and may include the following:

1. Asking ill people to voluntarily remain at home and not go to work or out in the community for about 7-10 days or until they are well and can no longer spread the infection to others (ill individuals will be treated with influenza antiviral medications, as appropriate, if these medications are effective and available).
2. Asking members of households with a person who is ill to voluntarily remain at home for about 7 days (household members may be provided with antiviral medications, if these medications are effective and sufficient in quantity and feasible mechanisms for their distribution have been developed).
3. Dismissing students from schools (including public and private schools as well as colleges and universities) and school-based activities and closure of childcare programs for up to 12 weeks, coupled with protecting children and teenagers through social distancing in the community to include reductions of out-of-school social contacts and community mixing. Childcare programs discussed in this guidance include centers or facilities that provide care to any number of children in a nonresidential setting, large family childcare homes that provide care for seven or more children in the home of the provider and small family childcare homes that provide care to six or fewer children in the home of the provider.¹
4. Recommending social distancing of adults in the community, which may include cancellation of large public gatherings; changing workplace environments and schedules to decrease social density and preserve a healthy workplace to the greatest extent possible

without disrupting essential services; ensuring work-leave policies to align incentives and facilitate adherence with the measures outlined above.

Recommendations for dismissing students from schools will depend upon the severity of the pandemic. The current three-tiered planning approach includes 1) no dismissals in a Category 1 pandemic, 2) short-term (up to four weeks) dismissal of students from schools during a Category 2 or Category 3 pandemic, and 3) prolonged (up to 12 weeks) dismissal of students from schools during a severe influenza pandemic (Category 4 or Category 5 pandemic).

In the most severe pandemic, the duration of these public health measures would likely be for 12 weeks, which would have educational implications for students. Planning now for a prolonged period of student dismissal may assist schools to be prepared as much as possible to provide opportunities for continued instruction and other assistance to students and staff. Federal, State, local, tribal, and territorial laws, regulations, and policies regarding student dismissal from schools school closures, funding mechanisms, and educational requirements should be taken into account in pandemic planning. If students are dismissed from school but schools remain open, school- and education-related assets, including school buildings, school kitchens, school buses, and staff, may continue to remain operational and potentially be of value to the community in many other ways. In addition, faculty and staff may be able to continue to provide lessons and other services to students by television, radio, mail, Internet, telephone, or other media. Continued instruction is not only important for maintaining learning but also serves as a strategy to engage students in a constructive activity during the time that they are being asked to remain at home.

Planning now for a severe pandemic will ensure that schools are prepared to implement the community interventions that may be recommended. Be prepared to activate the school district's crisis management plan for pandemic influenza that links the district's incident command system with the local and/or State

health department/emergency management system's incident command system(s).

The *Pandemic Flu Planning Checklist for K-12 School Districts* describes approaches to school planning for a pandemic and can be found at <http://www.pandemicflu.gov/plan/school/index.html> and <http://www.ed.gov/admins/lead/safety/emergencyplan/pandemic/planning-guide/index.html>. Recommendations for implementation of pandemic mitigation strategies are available at www.pandemicflu.gov, and reliable, accurate, and timely information on the status and severity of a pandemic will also be posted on the Web site. Additional information is available from the Centers for Disease Control and Prevention (CDC) Hotline: 1-800-CDC-INFO (1-800-232-4636). This line is available in English and Spanish, 24 hours a day, 7 days a week. TTY: 1-888-232-6348. Questions can be e-mailed to cdcinfo@cdc.gov.

1. Plan for ill individuals to remain at home

- Develop a plan for faculty and staff absences due to personal illness. Plan for alternative staffing:
 - Identify critical job functions and plan for alternate coverage of those functions during a pandemic.
 - Review and analyze Federal and State employment laws that identify employer obligations and options for personnel.
- Establish and clearly communicate policies on sick leave and employee compensation.
- Encourage ill persons to stay home during a pandemic and establish return-to-work policies after illness.
- Establish policies for sick-leave absences unique to a pandemic (e.g., liberal/unscheduled leave).
- Develop policies on observation for illness and what to do when a student or staff member becomes ill at the workplace.
- Advise employees to look for information on taking care of ill people at home. Such information will be posted on www.pandemicflu.gov.

2. Plan for all household members of a person who is ill to voluntarily remain at home

- Develop a plan for faculty and staff absences related to family member illness. Plan for alternate staffing:
 - Identify critical job functions and plan now for coverage of those functions.
 - Establish policies for alternate or flexible worksite (e.g., videoconferencing and teleworking) and flexible work hours.
 - Review Federal and State employment laws that identify your employer obligations and options for employees.
- Establish and clearly communicate policies on family leave and employee compensation.
- Establish policies for sick-leave absences unique to a pandemic (e.g., liberal/unscheduled leave).
- Establish policies for employees who have to stay home because someone in their household is ill with pandemic influenza.
- Be familiar with Federal and State laws regarding leave of workers who need to care for an ill family member or voluntarily remain at home.
- Advise employees to look for information on taking care of ill people at home. Such information will be posted on www.pandemicflu.gov.

3. Plan for dismissal of students and childcare closure for employees

- Develop a plan for school operations during all levels of pandemic severity. Even if students are dismissed, schools may remain operational.
- Identify and plan for employees and staff who may have to stay home if schools and childcare programs dismiss students/children during a pandemic.
- Plan for alternate staffing based on your assessment.
 - Identify critical job functions and plan now for coverage of those functions in case of prolonged absenteeism during a pandemic.
 - Establish policies for employees to possibly work flexible work hours and schedules (e.g., staggered shifts) to accommodate their childcare needs.

- Encourage your employees who have children to make their own plans to care for children if officials recommend dismissal of students from schools and closure of childcare programs. Advise that employees plan for an extended period (up to 12 weeks) in case the pandemic is severe. Instruct employees not to bring their children to the workplace if childcare cannot be arranged.
- In a severe pandemic, parents would be advised to protect their children by reducing out-of-school social contacts and mixing with other children. Although limiting all outside contact may not be feasible, families may be able to develop support systems with co-workers, friends, families, or neighbors if they continue to need childcare. For example, they could prepare a plan in which two to three families work together to supervise and provide care for a small group of infants and young children while their parents are at work (studies suggest that childcare group size of less than six children may be associated with fewer respiratory infections).²
- Determine if schools must, may, or cannot compensate, continue benefits, and extend leave to employees who are not working during the pandemic. Inform employees of the decision.
- Work with your State legislatures if modifications to State laws are needed for flexibilities regarding, for example, requirements for the number of instruction days, amount of instruction time, and length of the school day.
- Work with State and local governments and faith-based and community-based organizations to provide any needed assistance to staff who cannot report to work for a prolonged period.

4. Plan for dismissal of students

- Develop a plan for continuity of instruction
- Inform teachers, students and parents how alternate learning opportunities will be provided.
 - This may include assignments by radio, television, regular mail, e-mail, telephone, and teleconferencing or through the media
 - Consider potential restructuring of the school calendar

- Provide school nurses, counselors, school psychologists, special-needs teachers, and social workers guidance on maintaining needed health, counseling, and social services for students with physical and mental/emotional healthcare needs.
- Identify and inform parents on how students who need free meals may qualify for other types of nutrition assistance in the community.
- Provide systematic emergency communications to school staff and families during the pandemic, using a telephone calling tree, an e-mail alert, call-in voice recording, or regular mail to communicate.

5. Plan for workplace and community social distancing measures

- Become familiar with social distancing actions that may be used during a pandemic to modify frequency and type of person-to-person contact (e.g., reducing hand-shaking, limiting face-to-face meetings, promoting teleworking, liberal/unscheduled leave policies, and staggered shifts).
- Plan to operate the workplace using social distancing and other measures to minimize close contact between employees.
- Review and implement guidance from the Occupational Safety and Health Administration (OSHA) on appropriate work practices and precautions to protect employees from occupational exposure to influenza virus during a pandemic. Risks of occupational exposure to influenza virus depends in part on whether jobs require close proximity to people who may be infectious with the pandemic influenza virus or whether employees are required to have either repeated or extended contact with the general public. OSHA will post and periodically update such guidance on www.pandemicflu.gov.
- Encourage good hygiene at the workplace. Provide students, faculty, and staff with information about the importance of hand hygiene (information can be found at <http://www.cdc.gov/cleanhands/>) as well as convenient access to soap and water and alcohol-based hand gel in your facility. Educate employees and students about covering their cough to prevent the spread of germs (see <http://www.cdc.gov/flu/protect/covercough.htm>).
- Promote social distancing of children and teens outside the school setting by advising they reduce their social interaction and contacts to the greatest extent possible. This may include cancelling after-school and extracurricular group activities.

6. Communicate with faculty, staff, students, and parents/families

- Make sure your school's pandemic plan is explained and understood by faculty, staff, and parents in advance of a pandemic, including expected roles/actions for employees and others during implementation.
- Provide information to school staff and parents/families on what they can do to prepare themselves and their families for the pandemic. Resources are available at <http://www.pandemicflu.gov/plan/individual/checklist.html> and www.ready.gov/america/index.html.
 - Be prepared to provide parents/families with information discussing student dismissal from school and the importance of keeping students from congregating with other students in out-of-school settings.
- Provide staff with information on the school district's plan for
 - Assuring that essential central office functions, including payroll, and communications with staff, students, and families will continue.
 - Adapting school facilities to supplement healthcare delivery if needed by local public health officials.
 - Encouraging school nurses, counselors, school psychologists, and social workers to establish supportive long-distance relationships with particularly vulnerable students via the phone, e-mail, or regular mail.
- Coordinate strategies with other districts in your region.

7. Help your community

- Coordinate your pandemic plans and actions with local health and community planning.
- Find volunteers in your school who want to help people in need, such as elderly neighbors, single parents of small children, or people without the resources to get the medical or other help they will need.
- Think of ways your school others in your community to help them plan for a pandemic.
- Participate in community-wide exercises to enhance pandemic preparedness.

8. Recovery

- Establish the criteria and procedure with State and local planning teams for resuming school activities.
- Develop communication for advising employees, students, and families of the resumption of school programs and activities.
- Develop the procedures, activities, and services needed to restore the learning environment.

References:

¹ American Academy of Pediatrics. Children in Out-of-Home Child Care: Classification of Care Service. In: Pickering LK, ed. Red Book: 2003 Report of the Committee on Infectious Diseases. 26th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2003:124.

² Bradley RH. Child care and common communicable illnesses in children aged 37 to 54 months. Arch Pediatr Adolesc Med. 2003 Feb;157(2):196-200.

Appendix 7 - Pandemic Influenza Community Mitigation Interim Planning Guide for Colleges and Universities

Purpose

This Interim Planning Guide for Colleges and Universities is provided as a supplement to the *Interim Pre-Pandemic Planning Guidance: Community Strategy for Pandemic Influenza Mitigation in the United States—Early, Targeted, Layered Use of Nonpharmaceutical Interventions*. The guide is intended to assist in pre-pandemic planning. Individuals and families, employers, schools, and other organizations will be asked to take certain steps (described below) to help limit the spread of a pandemic, mitigate disease and death, lessen the impact on the economy, and maintain societal functioning. This guidance is based upon the best available current data and will be updated as new information becomes available. During the planning process, Federal, State, local, tribal, and territorial officials should review the laws, regulations, and policies that relate to these recommendations, and they should include stakeholders in the planning process and resolution of issues.

Colleges and universities will be essential partners in protecting the public's health and safety when an influenza pandemic occurs. This *Pandemic Influenza Community Mitigation Interim Planning Guide for Colleges and Universities* provides guidance to post-secondary institutions, describing how they should prepare for an influenza pandemic. At the onset of an influenza pandemic, public health officials will determine the severity of the pandemic and recommend actions to protect the community's health. People who become severely ill may need to be cared for in a hospital. However, most people with influenza will be safely cared for at home.

Community mitigation recommendations will be based on the severity of the pandemic and may include the following:

1. Asking ill people to voluntarily remain at home and not go to work or out in the community for about 7-10 days or until they are well and can no longer spread the infection to others (ill individuals will be treated with influenza antiviral medications, as appropriate, if these medications are effective and available).
2. Asking members of households with a person who is ill to voluntarily remain at home for about 7 days (household members may be provided with antiviral medications, if these medications are effective and sufficient in quantity and feasible mechanisms for their distribution have been developed).
3. Dismissing students from schools (including public and private schools as well as colleges and universities) and school-based activities and closure of childcare programs for up to 12 weeks, coupled with protecting children and teenagers through social distancing in the community to include reductions of out-of-school social contacts and community mixing. Childcare programs discussed in this guidance include centers or facilities that provide care to any number of children in a nonresidential setting, large family childcare homes that provide care for seven or more children in the home of the provider and small family childcare homes that provide care to six or fewer children in the home of the provider.¹
4. Recommending social distancing of adults in the community, which may include cancellation of large public gatherings; changing workplace environments and schedules to decrease social density and preserve

a healthy workplace to the greatest extent possible without disrupting essential services; and ensuring work-leave policies to align incentives and facilitate adherence with the measures outlined above.

Recommendations for dismissing students from college and university classes will depend upon the severity of the pandemic. The current three-tiered planning approach includes 1) no dismissals, 2) short-term (up to 4 weeks) dismissal from classes in a Category 2 or Category 3 pandemic, and 3) prolonged (up to 12 weeks) dismissal from classes in a severe influenza pandemic (Category 4 or Category 5).

Dismissing students for up to 12 weeks will have educational implications. Planning now for a prolonged period of student dismissal will help colleges and universities to plan for alternate ways to provide continued instruction and services for students and staff. Even if students are dismissed from classes, the college/university facility may remain open during a pandemic and may continue to provide services to students who must remain on campus and provide lessons and other services to off-campus students via Internet or other technologies. Some students, particularly international students, may not be able to rapidly relocate during a pandemic and may need to remain on campus for some period. They would continue to need essential services from the college/university during that time.

Continued instruction is not only important for maintaining learning but also serves as a strategy to reduce boredom and engage students in a constructive activity while group classes are cancelled. Planning now for a severe pandemic will help assure that your college or university is prepared to implement these community recommendations. These preparedness efforts will be beneficial to your school, staff, students, and the community, regardless of the severity of the pandemic. Be prepared to activate the university's crisis management plan for pandemic influenza, which links the university's incident command system with the local and/or State health department/emergency management system's incident command system(s).

The *Pandemic Flu Planning Checklist for Colleges*

and *Universities* describes approaches to school planning for a pandemic and can be found at <http://www.pandemicflu.gov/plan/school/index.html> and <http://www.ed.gov/admins/lead/safety/emergencyplan/pandemic/planning-guide/index.html>. Recommendations for implementation of pandemic mitigation strategies are available at www.pandemicflu.gov, and reliable, accurate, and timely information on the status and severity of a pandemic will also be posted on this site. Additional information is available from the Centers for Disease Control and Prevention (CDC) Hotline: 1-800-CDC-INFO (1-800-232-4636). This line is available in English and Spanish, 24 hours a day, 7 days a week. TTY: 1-888-232-6348. Questions can be e-mailed to cdcinfo@cdc.gov.

Planning Recommendations

1. Plan for ill individuals to remain at home

- Develop a plan for faculty and staff absences due to personal illness. Plan for alternative staffing.
 - Identify critical job functions and plan for alternate coverage of those functions during a pandemic.
 - Review and analyze Federal and State employment laws that identify employer obligations and options for personnel.
- Establish and clearly communicate policies on sick leave and employee compensation.
- Encourage ill persons to stay home during a pandemic and establish return-to-work policies after illness.
- Establish policies for sick-leave absences unique to a pandemic (e.g., liberal/unscheduled leave).
- Develop policies on observation for illness and what to do when a student or staff member becomes ill at the college/university.
- Advise employees to look for information on taking care of ill people at home. Such information will be posted on www.pandemicflu.gov.

2. Plan for all household members of a person who

is ill to voluntarily remain at home

- Develop a plan for faculty and staff absences related to family member illness. Plan for alternate staffing.
 - Identify critical job functions and plan now for coverage of those functions.
 - Establish policies for alternate or flexible worksite (e.g., videoconferencing and teleworking) and flexible work hours.
 - Review Federal and State employment laws that identify your employer obligations and options for employees.
- Establish and clearly communicate policies on family leave and employee compensation.
- Establish policies for sick-leave absences unique to a pandemic (e.g., liberal/unscheduled leave).
- Establish policies for employees who have to stay home because someone in their household is ill with pandemic influenza.
- Be familiar with Federal and State laws regarding leave of workers who need to care for an ill family member or voluntarily remain at home.
- Advise employees to look for information on taking care of ill people at home. Such information will be posted on www.pandemicflu.gov.

3. Plan for dismissal of students and childcare closure for employees

- Identify and plan for employees and staff who may have to stay home if schools and childcare programs dismiss students/children during a severe pandemic.
- Plan for alternate staffing based on your assessment.
 - Identify critical job functions and plan for coverage of those functions in case of prolonged absenteeism during a pandemic.
 - Establish flexible work policies for employees, such as flexible work hours and schedules (e.g., staggered shifts) to accommodate childcare needs.
- Encourage your employees who have children to make their own plans to care for children if officials recommend dismissal of students from

schools and closure of childcare programs.

Advise that employees plan for an extended period (up to 12 weeks) in case the pandemic is severe. Instruct employees not to bring their children to the workplace if childcare cannot be arranged.

- In a severe pandemic, parents will be advised to protect their children by reducing out-of-school social contacts and mixing with other children. Although limiting all outside contact may not be feasible, families may be able to develop support systems with co-workers, friends, families, or neighbors, if they continue to need childcare. For example, they could prepare a plan in which two to three families work together to supervise and provide care for a small group of infants and young children while their parents are at work (studies suggest that childcare group size of less than six children may be associated with fewer respiratory infections).²
- Determine if schools must, may, or cannot compensate, continue benefits to and extend leave to employees who are not working during the pandemic. Inform employees of the decision.
- Coordinate with State and local government and faith-based and community-based organizations to assist staff that are not able to work for a prolonged period.

4. Plan for dismissal of students

- Inform students about plans and procedures for providing and completing course work.
- Provide guidance to students and faculty on continuing student instruction. Such guidance may include
 - Assessing the possibility of altering course-work requirements.
 - Providing ongoing assignments by regular mail, e-mail, Internet links, telephone, teleconferencing, or calling into a recorded message at the university
 - Gathering information in advance that would identify students' mailing addresses, telephone/cell numbers, and e-mail addresses
- Encouraging faculty who teach the same subject to share in the development of distance-learning

instructional materials for their students.

- Providing information on accessing university healthcare staff (e.g., nurses, nurse practitioners, physicians, physician assistants, counselors, and psychologists) who could be recommended as consultation resources for students with physical and mental/emotional healthcare needs.
- Develop a plan for accommodating students, especially international students, who remain on campus during an influenza pandemic.
- Review and implement guidance from the Occupational Safety and Health Administration (OSHA) on appropriate work practices and precautions to protect employees from occupational exposure to influenza virus during a pandemic. Risks of occupational exposure to influenza virus depends in part on whether or not jobs require close proximity to people who may be infectious with the pandemic influenza virus or whether employees are required to have either repeated or extended contact with the public. OSHA will post and periodically update such guidance on www.pandemicflu.gov.

5. Plan for workplace and community social distancing measures

- Learn about social distancing methods that may be used during a pandemic to limit person-to-person contact during a pandemic and reduce the spread of disease (e.g., reducing hand-shaking, limiting face-to-face meetings and shared workstations, work from home policies, staggered shifts).
- Use social distancing measures to minimize close contact at your college/university. Determine how your facility could be rearranged to allow more distance between people during a pandemic.
- Develop plans for alternatives to mass gatherings. Examples could range, for example, from video messages on the Internet to e-mailed messages, mailed newsletters, pre-recorded messages on a designated call-in phone number.
- Encourage good hygiene at the workplace. Provide faculty, staff, and students with information about the importance of hand hygiene (information can be found at <http://www.cdc.gov/cleanhands/>) as well as convenient access to soap and water and alcohol-based hand gel in your facility. Educate faculty, staff, and students about covering their cough to prevent the spread of germs (see <http://www.cdc.gov/flu/protect/covercough.htm>).

6. Communicate with faculty, staff, students, and parents/families

- Provide faculty, staff, and parents with information on the college/university's pandemic preparedness plan in advance of a pandemic. This communication should include
 - Identifying expected roles/actions for faculty, staff, students, and other stakeholders during implementation
 - Assuring that essential central office functions, including payroll, and communications with staff, students and families will continue
 - Identifying how the college/university's physical facilities may be used for other purposes during a pandemic
- Develop a plan to inform parents/families that students may be dismissed during a Category 4-5 pandemic.
 - Encourage them to plan for that contingency, including plans for relocating students to home or elsewhere
 - Inform them of school procedures and policies regarding tuition, fees, and contractual obligations
- Provide systematic emergency communications to faculty, staff, and students (both on and off campus) during the pandemic by using multiple methods (e.g., a telephone calling tree, an e-mail alert, or call-in voice recording) to communicate pandemic status in the community and status of classes and other university activities.
- Be prepared to provide parents/families with information discussing
 - How dismissal of students will be announced
 - Why students will be dismissed from classes and the importance of keeping students from congregating with others in the community
 - How alternate instruction will be provided
- Be prepared to provide students who soon will be leaving for home with information discussing

- Why students are being dismissed from classes and the importance of keeping students from congregating with other students in the community. Students should understand
 - Differences between seasonal and pandemic influenza
 - How influenza is spread
 - What individuals can do help prevent the spread of influenza
- Remind students who live in residence halls to take their books and other personal items with them on the last day of classes, if indicated.
- Provide information to university faculty, staff, and parents/families on what they can do to prepare their families for the pandemic. Resources are available at <http://www.pandemicflu.gov/plan/individual/checklist.html> and www.ready.gov/america/index.html.
- Recommend that faculty, staff, students and their families seek further information about the pandemic through resources, including key Federal, State, and local public health that provide regular updates on the status of the pandemic. For reliable, accurate, and timely information about pandemic flu, see www.pandemicflu.gov.
- Develop communication for advising employees and students and families of the resumption of school programs and activities.
- Develop the procedures, activities, and services needed to restore the learning environment.

References:

¹ American Academy of Pediatrics. Children in Out-of-Home Child Care: Classification of Care Service. In: Pickering LK, ed. Red Book: 2003 Report of the Committee on Infectious Diseases. 26th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2003:124.

² Bradley RH. Child care and common communicable illnesses in children aged 37 to 54 months. Arch Pediatr Adolesc Med. 2003 Feb;157(2):196-200.

7. Help your community

- Coordinate your pandemic plans and actions with local health planning.
- Find volunteers in your college/university who want to help people in need, such as elderly neighbors, single parents of small children, or people without the resources to get the medical or other help they will need.
- Think of ways your institution can reach out to others in your community to help them plan for a pandemic.
- Participate in community-wide exercises to enhance pandemic preparedness.

8. Recovery

- Establish with State and local planning teams the criteria and procedures for resuming college/university activities.

Appendix 8 - Pandemic Influenza Community Mitigation Interim Planning Guide for Faith-Based and Community Organizations

Purpose

This Interim Planning Guide for Faith-based and Community Organizations is provided as a supplement to the *Interim Pre-Pandemic Planning Guidance: Community Strategy for Pandemic Influenza Mitigation in the United States—Early, Targeted, Layered Use of Nonpharmaceutical Interventions*. The guide is intended to assist in pre-pandemic planning. Individuals and families, employers, schools, and faith-based and community organizations will be asked to take certain steps (described below) to help limit the spread of a pandemic, mitigate disease and death, lessen the impact on the economy, and maintain societal functioning. This guidance is based upon the best available current data and will be updated as new information becomes available. During the planning process, Federal, State, local, tribal, and territorial officials should review the laws, regulations, and policies that relate to these recommendations, and they should include stakeholders in the planning process and resolution of issues.

Faith-based and community organizations (FBCOs) will be essential partners in protecting the public's health and safety when an influenza pandemic occurs. This *Pandemic Influenza Community Mitigation Interim Planning Guide for Faith-Based and Community Organizations* provides guidance for religious organizations (including, for example, places of worship—churches, synagogues, mosques, and temples—and faith-based social service providers), social service agencies, and community organizations in preparing for and responding to an influenza pandemic. When an influenza pandemic starts, public health officials will determine the severity of the pandemic and recommend actions to protect the

community's health. People who become severely ill may need to be cared for in a hospital. However, most people with influenza will be safely cared for at home.

Community mitigation recommendations will be based on the severity of the pandemic and may include the following:

1. Asking ill people to voluntarily remain at home and not go to work or out in the community for about 7-10 days or until they are well and can no longer spread the infection to others (ill individuals will be treated with influenza antiviral medications, as appropriate, if these medications are effective and available).
2. Asking members of households with a person who is ill to voluntarily remain at home for about 7 days (household members may be provided with antiviral medications, if these medications are effective and sufficient in quantity and feasible mechanisms for their distribution have been developed).
3. Dismissing students from schools (including public and private schools as well as colleges and universities) and school-based activities and closure of childcare programs for up to 12 weeks, coupled with protecting children and teenagers through social distancing in the community to include reductions of out-of-school social contacts and community mixing. Childcare programs discussed in this guidance include centers or facilities that provide care to any number of children in a nonresidential setting, large family childcare homes that provide care for seven or more children in the home of the provider and small family childcare homes that provide care to six or fewer children in the home of the provider.¹

4. Recommending social distancing of adults in the community, which may include cancellation of large public gatherings; changing workplace environments and schedules to decrease social density and preserve a healthy workplace to the greatest extent possible without disrupting essential services; and ensuring work-leave policies to align incentives and facilitate adherence with the measures outlined above.

Planning now for a severe pandemic will help assure that your organization is prepared to implement these community recommendations. These preparedness efforts will be beneficial to your organization, volunteer and paid staff, and community, regardless of the severity of the pandemic. The *Faith-Based & Community Organizations Pandemic Influenza Preparedness Checklist* (available at <http://www.pandemicflu.gov/plan/community/faithcomchecklist.html>) provides an approach to pandemic planning by FBCOs. In addition, recommendations for implementation of pandemic mitigation strategies are available at www.pandemicflu.gov. Reliable, accurate, and timely information on the status and severity of the pandemic also will be posted on www.pandemicflu.gov. Additional information is available from the Centers for Disease Control and Prevention (CDC) Hotline: 1-800-CDC-INFO (1-800-232-4636). This line is available in English and Spanish, 24 hours a day, 7 days a week. TTY: 1-888-232-6348. Questions can be e-mailed to cdcinfo@cdc.gov.

Planning Recommendations

1. Plan for ill individuals to remain at home

- Plan for employee and volunteer staff absences during a pandemic due to personal illness.
 - Identify critical job functions and plan how to temporarily suspend non-critical activities, cross-train staff to cover critical functions, and cover the most critical functions with fewer staff.
 - Identify employees, volunteers, and members or clients that live alone or might need extra assistance if they need to stay home because they are ill.
 - Review Federal and State employment laws

that identify your employer obligations and options for employees.

- Establish and clearly communicate policies on sick leave and employee compensation.
- Encourage ill persons to stay home during a pandemic and establish return to work policies after illness.
- Encourage leadership to model staying at home when ill as well as the use of proper cough and sneeze etiquette and hand hygiene.
- Where appropriate, align public health messages and recommendations with your organization's values and beliefs. For example, develop a culture that recognizes the positive behaviors of voluntarily staying home when ill to get well and avoid spreading infection to others.
- Develop policies on what to do when a person becomes ill at the workplace.
- Advise employees, volunteers, and members or clients to look for information on taking care of ill people at home. Such information will be posted on www.pandemicflu.gov.

2. Plan for all household members of a person who is ill to voluntarily remain at home

- Plan for employee and volunteer staff absences during a pandemic related to family member illness.
 - Identify critical job functions and plan how to temporarily suspend non-critical activities, cross-train staff to cover critical functions, and cover the most critical functions with fewer staff.
 - Establish policies for alternate or flexible worksite (e.g., work via the Internet, e-mail, mailed or phone work assignments) and flexible work hours.
- Establish and clearly communicate policies on family leave and employee compensation, especially Federal laws and laws in your State regarding leave of workers who need to care for an ill family member or voluntarily remain at home.
- Establish and clearly communicate policies for volunteers to ensure that critical functions are covered.

- Advise staff and members to look for information on taking care of ill people at home. Such information will be posted on www.pandemicflu.gov.

3. Plan for dismissal of students and childcare closure

- Find out how many employee and volunteer staff may have to stay at home to care for children if schools and childcare programs dismiss students.
 - Identify critical job functions and plan for temporarily suspending non-critical activities and cross-training staff to cover critical functions with fewer staff.
 - Establish policies for staff with children to work from home, if possible, and consider flexible work hours and schedules (e.g., staggered shifts).
- Encourage staff with children to make plans for what they will do if officials recommend dismissal of students from schools and closure of childcare programs. Instruct staff and volunteers not to bring their children to the workplace if childcare cannot be arranged.
- In a severe pandemic, parents will be advised to protect their children by reducing out-of-school social contacts and mixing with other children. Although limiting all outside contact may not be feasible, parents may be able to develop support systems with co-workers, friends, families, or neighbors, if they continue to need childcare. For example, they could prepare a plan in which two to three families work together to supervise and provide care for a small group of infants and young children while their parents are at work (studies suggest that childcare group size of less than six children may be associated with fewer respiratory infections).²
- Help your staff explore about benefits they may be eligible for if they have to stay home to mind children for a prolonged period during a pandemic.

4. Prepare your organization

- Consider potential financial deficits due to emergencies when planning budgets. This is useful for pandemic planning and many other unforeseen emergencies, such as fires and natural disasters.
- Many FBCOs rely on community-giving to support their activities. Develop strategies that will allow people to continue to make donations and contributions via the postal service, the Internet, or other means if they are at home for an extended period.
- Develop a way to communicate with your employee and volunteer staff during an emergency to provide information and updates.
- Meet with other FBCOs to develop collaborative efforts to keep your organizations running, such as large organizations collaborating with small ones or several small organizations working together.

5. Plan for workplace and community social distancing measures

- Learn about social distancing methods that may be used during a pandemic to limit person-to-person contact during a pandemic and reduce the spread of disease (e.g., reducing hand-shaking, limiting face-to-face meetings and shared workstations, work from home policies, staggered shifts).
- Use social distancing measures to minimize close contact at your facility. Determine how your facility could be rearranged to allow more distance between people during a pandemic.
- Develop plans for alternatives to mass gatherings. Examples could range from video messages on the Internet to e-mailed messages, mailed newsletters, pre-recorded messages from trusted leaders on a designated call-in phone number, and daily teaching guides from trusted leaders.
- Encourage good hygiene at the workplace. Provide staff, volunteers, and members with information about the importance of hand hygiene (information can be found at <http://www.cdc.gov/cleanhands/>) as well as convenient access to soap and water and alcohol-based hand gel in your

facility. Educate employees about covering their cough to prevent the spread of germs (see <http://www.cdc.gov/flu/protect/covercough.htm>).

- Identify activities, rituals, and traditions, such as hand shaking, hugging, and other close-proximity forms of greeting, that may need to be temporarily suspended or modified during a pandemic.
- Review and implement guidance from the Occupational Safety and Health Administration (OSHA) to adopt appropriate work practices and precautions to protect employees from occupational exposure to influenza virus during a pandemic. Risks of occupational exposure to influenza virus depends in part on whether or not jobs require close proximity to people potentially infected with the pandemic influenza virus or whether they are required to have either repeated or extended contact with the general public. OSHA will post and periodically update such guidance on www.pandemicflu.gov.

6. Communicate with your employee and volunteer staff and members

- Share your organization's pandemic plan, including expected roles/actions for employee and volunteer staff and members during implementation.
- Suggest that all employee, volunteers, and members or clients prepare for a pandemic. Resources are available at <http://www.pandemicflu.gov/plan/individual/checklist.html> and www.ready.gov/america/index.html. For example, individuals and families should have a reserve supply of food and water. People with more resources might consider obtaining enough supplies to support 1-2 other families in an emergency.
- Ensure that your organization has up-to-date contact information for employees, volunteers, and members or clients, including names of family members, addresses, home, work, and cell phone numbers, e-mail addresses, and emergency contacts.

7. Help your Community

- Identify people who are vulnerable and may need assistance in your community (i.e., elderly people who live alone, persons with disabilities, people with limited skill in speaking English, low-income families, children, or teens who may lack supervision). Designate people from your organization to be responsible to check on specific vulnerable people or families.
- Determine ways your facility might be used during a pandemic, such as a temporary care facility or a central distribution site for providing meals, supplies, or medicine to those who cannot obtain them.
- Identify and meet with local emergency responders, health departments, and healthcare organizations to learn about their planning and educate them about your organization's planning.
- Suggest that each household maintain a current list of emergency contacts in your community.
- Meet with other FBCOs to develop collaborative efforts to care for those in need, such as large organizations partnering with small ones or several small organizations working together.
- Identify employee and volunteer staff in advance who would be willing to help others in need during a pandemic and help them to receive training through the local health department, emergency services, or other resources.
- Designate an experienced person who can take calls and organize individuals who call spontaneously to volunteer during an emergency to facilitate the best use of their particular skills and experience.
- Develop or identify an existing mental health or counseling hotline that people in the community can call during a pandemic or other emergency.
- Participate in community-wide exercises to enhance pandemic preparedness.

8. Recovery

- Assess which criteria would need to be met to resume normal operations.
- Plan for the continued need for medical, mental health, and social services after a pandemic.

References:

¹ American Academy of Pediatrics. Children in Out-of-Home Child Care: Classification of Care Service. In: Pickering LK, ed. Red Book: 2003 Report of the Committee on Infectious Diseases. 26th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2003:124.

²Bradley RH. Child care and common communicable illnesses in children aged 37 to 54 months. Arch Pediatr Adolesc Med. 2003 Feb;157(2):196-200.

Appendix 9 - Pandemic Influenza Community Mitigation Interim Planning Guide for Individuals and Families

Purpose

This Interim Planning Guide for Individuals and Families is provided as a supplement to the *Interim Pre-Pandemic Planning Guidance: Community Strategy for Pandemic Influenza Mitigation in the United States—Early, Targeted, Layered Use of Nonpharmaceutical Interventions*. The guide is intended to assist in pre-pandemic planning. Individuals and families, employers, schools, and other organizations will be asked to take certain steps (described below) to help limit the spread of a pandemic, mitigate disease and death, lessen the impact on the economy, and maintain societal functioning. This guidance is based upon the best available current data and will be updated as new information becomes available. During the planning process, Federal, State, local, tribal, and territorial officials should review the laws, regulations, and policies that relate to these recommendations, and they should include stakeholders in the planning process and resolution of issues.

Individuals and families will have an essential role in protecting themselves and the public's health and safety when an influenza pandemic occurs. This *Pandemic Influenza Community Mitigation Interim Planning Guide for Individuals and Families* provides guidance describing how individuals and families might prepare for and respond to an influenza pandemic. At the onset of an influenza pandemic, public health officials will determine the severity of the pandemic and recommend actions to protect the community's health. People who become severely ill may need to be cared for in a hospital. However, most people with influenza will be safely cared for at home.

Community mitigation recommendations will be based on the severity of the pandemic and may include the following:

1. Asking ill people to voluntarily remain at home and not go to work or out in the community for about 7-10 days or until they are well and can no longer spread the infection to others (ill individuals will be treated with influenza antiviral medications, as appropriate, if these medications are effective and available).
2. Asking members of households with a person who is ill to voluntarily remain at home for about 7 days (household members may be provided with antiviral medications, if these medications are effective and sufficient in quantity and feasible mechanisms for their distribution have been developed).
3. Dismissing students from schools (including public and private schools as well as colleges and universities) and school-based activities and closure of childcare programs for up to 12 weeks, coupled with protecting children and teenagers through social distancing in the community to include reductions of out-of-school social contacts and community mixing. Childcare programs discussed in this guidance include centers or facilities that provide care to any number of children in a nonresidential setting, large family childcare homes that provide care for seven or more children in the home of the provider and small family childcare homes that provide care to six or fewer children in the home of the provider.¹
4. Recommending social distancing of adults in the community, which may include cancellation of large public gatherings; changing workplace environments and schedules to decrease social density and preserve a healthy workplace to the greatest extent possible

without disrupting essential services; and ensuring work-leave policies to align incentives and facilitate adherence with the measures outlined above.

Planning now for a severe pandemic will assist you and your family as you prepare for interventions that might be recommended. Resources are available at <http://www.pandemicflu.gov/plan/individual/checklist.html> and www.ready.gov/america/index.html. In addition, reliable, accurate, and timely information on the status and severity of a pandemic and recommendations for implementation of pandemic mitigation strategies is available at www.pandemicflu.gov. Additional information is available from the Centers for Disease Control and Prevention (CDC) Hotline: 1-800-CDC-INFO (1-800-232-4636). This line is available in English and Spanish, 24 hours a day, 7 days a week. TTY: 1-888-232-6348. Questions can be e-mailed to cdcinfo@cdc.gov.

Planning Recommendations

1. Plan for ill individuals to remain at home

- Be prepared to stay at home if you are ill with pandemic influenza. Information on taking care of ill people at home will be posted on www.pandemicflu.gov.
 - It will be important to have extra supplies on hand during a pandemic, as you may not be able to get to a store or stores may be out of supplies. You should have a reserve of at least a two-week supply of water and food; however, if the pandemic is severe, community disruption may last for a longer period. If community water supplies are not suitable for consumption during a pandemic, your local water utility or public health authorities will notify the community.
 - Periodically check your regular prescription drugs to ensure a continuous supply in your home.
 - Have any nonprescription drugs and other health supplies on hand, including a thermometer, pain relievers, stomach remedies, cough and cold medicines, and other over-the-counter medicines that you and your family use on a regular basis.
- Designate one person in the household who could be the caregiver if anyone in the household becomes ill with pandemic influenza. Develop an alternate plan for someone to be the caregiver if that person becomes sick.
- Talk with neighbors, friends, and family about your plans for staying at home if you or someone in your household is ill. Share ideas.
- Ensure that each household has a current list of emergency contacts in your community, including mental health and counseling resources.

2. Plan for all household members of a person who is ill to voluntarily remain at home

- Be prepared to stay at home if someone in your household is ill. Information on taking care of ill people at home will be posted on www.pandemicflu.gov.
 - Have any nonprescription drugs and other health supplies on hand, including a thermometer, pain relievers, stomach remedies, cough and cold medicines, and other over-the-counter medicines that you and your family use on a regular basis.
 - Talk with family members and members of your household about how they would be cared for if they become ill and about what will be needed to care for them in your or their home.
 - Designate one person in the household who could be the caregiver if anyone in the household becomes ill with pandemic flu. Make plans for a backup if that person gets ill.
 - Consider how to care for people in your household with special needs in case the services they rely on are not available.
 - Talk with neighbors, friends, and family about your plans for staying at home if someone in your household is ill. Share ideas.
 - Ensure that each household has a current list of emergency contacts in your community, including mental health and counseling resources.

3. Plan for dismissal of students and childcare closure

- If you have children in your household, make plans for their care if officials recommend dismissal of students from schools and closure of childcare programs.
 - Plan and arrange now for who will care for children if schools and childcare programs dismiss students and children during a pandemic. Plan for an extended period (up to 12 weeks) in case the pandemic is severe.
 - Do not plan to bring children to the workplace if childcare cannot be arranged.
 - If you have children in a college or university, have a plan for the student to relocate or return home, if desired, or if the college/university dismisses students, at the onset of a Category 4-5 pandemic.
 - Plan home-learning activities and exercises. Have materials, such as books, on hand.
 - Public health officials will likely recommend that children and teenagers do not gather in groups in the community during a pandemic. Plan recreational activities that your children can do at home.
 - Find out now about the plans at your child's school or childcare facility during a pandemic.
- In a severe pandemic, parents will be advised to protect their children by reducing out-of-school social contacts and mixing with other children. Although limiting all outside contact may not be feasible, parents may be able to develop support systems with co-workers, friends, families, or neighbors, if they continue to need childcare. For example, they could prepare a plan in which two to three families work together to supervise and provide care for a small group of infants and young children while their parents are at work (studies suggest that childcare group size of less than six children may be associated with fewer respiratory infections).²

4. Plan for workplace and community social distancing measures

- Become familiar with social distancing actions that may be used during a pandemic to modify frequency and type of person-to-person contact (e.g., reducing hand-shaking, limiting face-to-face meetings, promoting teleworking, liberal/unscheduled leave policies, and staggered shifts).
- Talk to your employer
 - Talk to your employer about the pandemic influenza plan for your workplace to include issues about benefits, leave, telework, and other possible policies to go into effect during a pandemic.
 - Ask your employer about how your employer will continue during a pandemic if key staff cannot come to work.
 - Plan for the possible reduction or loss of income if you are unable to work or your place of employment is closed. Consider maintaining a cash reserve.
 - Check with your employer or union about leave policies for workers who are ill, live in a household with someone ill with pandemic influenza, or have to take off work to take care of children.
 - Find out if you can work from home.
 - Discuss alternative ways of holding meetings at work, including, for example, teleconferences, during a pandemic.
 - Find out how you will receive information from your employer during a pandemic.
- Prepare backup plans in case public gatherings, such as community events and meetings and worship services, are cancelled.
 - Talk with others in your community about other ways of communicating during a pandemic if public gatherings are cancelled.
 - Plan for recreational activities that you and your household members can do at home if community gatherings are cancelled during a pandemic.
 - Discuss with your faith-based organization or place of worship their plans for communicating with members during a pandemic.

5. Help others

- Prepare backup plans for taking care of loved ones who are far away.
- Find volunteers who want to help people in need, such as elderly neighbors, single parents of small children, or people without the resources to get the medical help they will need.
- Think of ways you can reach out to others in your neighborhood or community to help them plan for and respond to a pandemic.

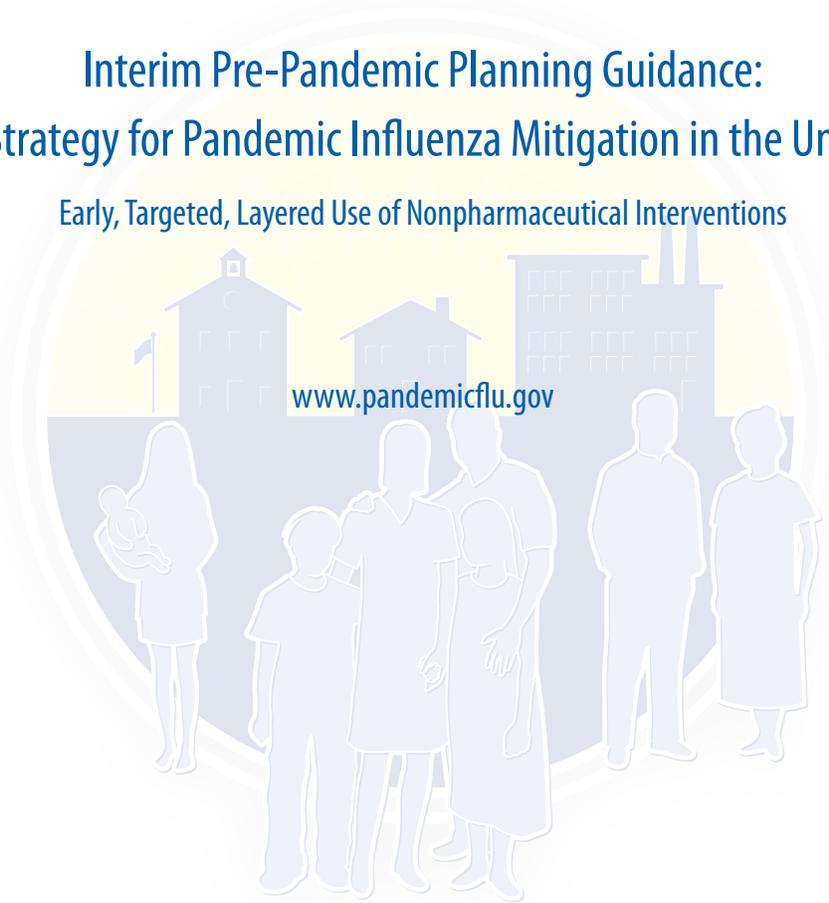
References:

¹American Academy of Pediatrics. Children in Out-of-Home Child Care: Classification of Care Service. In: Pickering LK, ed. Red Book: 2003 Report of the Committee on Infectious Diseases. 26th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2003:124.

²Bradley RH. Child care and common communicable illnesses in children aged 37 to 54 months. Arch Pediatr Adolesc Med. 2003 Feb;157(2):196-200.

Interim Pre-Pandemic Planning Guidance: Community Strategy for Pandemic Influenza Mitigation in the United States—

Early, Targeted, Layered Use of Nonpharmaceutical Interventions



February 2007



APPENDIX B

NEW JERSEY DEPARTMENT OF HEALTH
AND SENIOR SERVICES' *INFLUENZA*
SURGE CAPACITY GUIDANCE FOR
GENERAL HOSPITALS. 2006



State of New Jersey

DEPARTMENT OF HEALTH AND SENIOR SERVICES

OFFICE OF THE STATE EPIDEMIOLOGIST

PO BOX 369

TRENTON, N.J. 08625-0369

www.state.nj.us/health

RICHARD J. CODEY
Acting Governor

CLIFTON R. LACY, M.D.
Commissioner

November 9, 2004

Influenza Surge Capacity Guidance for General Hospitals

The purpose of this document is to provide guidance to general hospitals to better enable them to prepare for a surge in health care demand this season as a result of patients presenting with influenza.

Every year hospitals in New Jersey experience a surge in demand for services at the height of influenza season. It is not possible to predict the severity of an influenza season nor its impact on an individual hospital. The implementation of strategies to best manage surging patient volume is dependent on multiple factors. Administrators need to take into account both the absolute number of patients seeking medical attention, the intensity of services required by these patients, and the availability of staff and appropriate supplies. Much of the guidance offered below should be helpful in dealing with this expected seasonal surge. However, with a shortage of influenza vaccine this season, New Jersey hospitals need to be ready to deal not only with the normal seasonal increase in volume of hospital patients, but also with the potential for a more significant increase, which could be felt locally, regionally or statewide.

Should the increase in demand for the hospital's services be so large that it significantly impairs the ability of a hospital to offer its full array of regular services, the Department expects that the hospital will, as a result, activate its disaster plan and curtail all admissions for elective procedures. Should a hospital activate its disaster plan, it must notify the Department immediately at 1-800-792-9770. At the time of notification, the hospital should discuss with the Department any measures it plans to take that deviate from licensure standards. The Department will work cooperatively with facilities that have activated their disaster plans to ensure they have the maximum flexibility consistent with patient safety to respond to extraordinary service demands. Any anticipated deviation from the Emergency Medical Treatment and Labor Act (EMTALA) should be discussed with the Centers for Medicare and Medicaid Services (CMS), Region II at 1-212-264-1590.

In the guidance below, those recommendations that might entail deviations from licensure standards and presume an activated disaster plan are presented separately.

Surveillance

Health care facilities will play a key role in surveillance for influenza this season. Health care providers need to be alert to the signs and symptoms of influenza in patients presenting to their facility. Diagnostic testing for influenza should be considered in any individual presenting with pneumonia, severe respiratory illnesses, or influenza-like illnesses (ILI). Health care providers should receive education regarding the type of influenza testing available in the facility and the proper method of specimen collection. Diagnostic testing methods include the use of rapid diagnostic tests as well as more sensitive techniques, including polymerase chain reaction (PCR) and viral isolation. (<http://www.cdc.gov/flu/professionals/labdiagnosis.htm>) Rapid diagnostic tests are valuable because they allow the provider to make more informed and timely decisions regarding patient treatment and disposition. In addition, rapid testing might influence a provider's decision to offer antiviral prophylaxis to high risk contacts of the patient. Early identification is valuable to the public health community and might help to avert more widespread disease. The infection control professional should play an active role in surveillance and should be alerted to any positive influenza test result, any patient with suspected influenza, and any suspected death related to influenza in the facility.

Local health departments and the NJDHSS Communicable Disease Service are available for consultation, regarding outbreak identification and management; NJDHSS reminds health care facilities that any suspect or confirmed outbreak is reportable to local health departments, per N.J.A.C. 8:57. Finally, NJDHSS encourages health care facilities to regularly visit its website on influenza, including the influenza surveillance page (<http://www.state.nj.us/health/flu/surveillance.shtml>), for updated information on statewide ILI activity (including data from emergency departments) and new surveillance initiatives.

Transmission and Infection Control Strategies in the Health Care Facility

Observational studies and observations in hospitals indicate that transmission from one patient to others occurs most often in persons nearest the infected patient and that health care workers are important vehicles of transmission to patients on the same or different wards. These observations suggest that instituting contact and droplet precautions might be helpful. There is less data to support the clinical importance of isolation procedures (such as negative pressure rooms) to limit airborne transmission in the setting of normal air exchange. Further, the number of such rooms is limited and likely would be insufficient to handle the number of hospitalized patients expected with a surge in volume. Influenza viruses are known to survive on non-porous surfaces for up to 24 – 48 hours after contamination and on porous surfaces (tissues, cloth, paper) for up to 8 – 12 hours. Viable virus can be transferred from non-porous surfaces to hands for up to 24 hours after contact and from tissues to hands for up to 15 minutes after contact. The typical incubation period for influenza is two days (range one to four days). Viral shedding, and the period during which a person might be infectious to others, generally peaks on the second day of symptoms, but might begin the day before symptoms start, and typically lasts five to seven days in adults.

Recommended infection control precautions:

- Patients with ILI should be placed in a private room. When a private room is not available, patients with ILI may be cohorted. In an outbreak of influenza, most patients with suspected influenza will not have a specific laboratory diagnosis; such patients should be cohorted with other patients who have or might have influenza. If cohorting is not achievable, at least 3 feet spatial separation should be maintained between the infected patient and other patients and visitors. Special air handling and ventilation are not required.
- Health care personnel should use standard precautions as well as droplet and contact precautions. These precautions include hand washing, use of gloves, gowns, masks and eye protection as outlined by the CDC. (<http://www.cdc.gov/flu/professionals/infectioncontrol>).
- All individuals should wear a surgical mask upon entering the patient's room or when working within 3 feet of the patient. Remove the mask when leaving the patient's room and dispose of the mask in a waste container. N95 respirators, which would be recommended for infections with airborne spread such as tuberculosis, are not required for influenza. Individuals should wash their hands after mask removal.
- Limit the movement and transport of patients from the room for essential purposes only. If transport or movement is necessary, minimize patient dispersal of droplets by having the patient wear a surgical mask.
- The appropriate method and sequence of donning and doffing personal protective equipment should be reviewed with the staff.
- The facility should redouble efforts to comply with requirements to clean surfaces that have been contaminated with respiratory secretions with which staff or patients might subsequently come in contact (e.g., bedside tables, telephones).
- Staff should be educated about the epidemiology and prevention of influenza. Education should be a regularly scheduled event and should be repeated and geared toward a wide audience. Additional methods of education, including teleconferencing and mass mailing, may be considered. Extra effort should be made to ensure that all staff participates in this program, including nurses who work on a part-time basis, other staff who might not routinely care for patients but might be required to do so, volunteers, and non-patient care staff (e.g., staff who work in administrative, medical records, food service, environmental services departments, engineering, maintenance).
- Education should be provided to patients. Information on Universal Respiratory Precautions (<http://www.nj.gov/health/flu/education.shtml>) or Respiratory Etiquette (<http://www.cdc.gov/flu/protect/covercough.htm>) should be posted widely throughout the facility. Tissues and stations to facilitate hand hygiene should be made available throughout the facility.
- Visitors with ILI should be asked not to visit hospitalized patients. Signs should be posted outside the facility asking visitors with symptoms of influenza to defer visiting. Visitors with symptoms should be handed a mask or tissues at the door, if they must enter the facility, and be instructed on appropriate infection control practices.

- Visitors to an area with influenza-infected patients should receive educational material, should follow appropriate infection control practices, and be provided with appropriate PPE. Consideration should be given to restricting visits from children.

Isolation and quarantine are not recommended. They can be very effective in preventing the spread of infectious conditions but several substantial challenges may limit their usefulness during an influenza outbreak.

- The short incubation period for influenza makes it difficult to identify and quarantine contacts of influenza-infected case-patients before they become ill and have spread infection to others. By contrast, the longer incubation periods for smallpox (about 14 days) and SARS (up to 10 days) make this a more effective control strategy for those infections.
- The high rate of asymptomatic influenza illness (the majority of those infected) means that many potential disseminators of influenza will not be identified nor will their contacts.
- The wide range of clinical symptoms that might be expressed by influenza infected persons are common to many different pathogens and would necessitate isolation and quarantine of large numbers of persons, many of who would not be infected with influenza.

Emergency Department and Hospital-based Ambulatory Clinic Settings

As patient volume surges, crowded waiting areas might be a source of influenza transmission. Therefore, strict adherence to infection control practices in these settings is paramount. To prevent the transmission of influenza, it is important to implement infection control measures at the first point of contact. Personnel well trained in triage are vital. These individuals will play a key role in maintaining the integrity of the health care delivery system.

Potential strategies to help manage influenza patients in these settings include:

A. Minimal Interventions to Prevent Exposure

- At a minimum, patients should be asked to self-report influenza-like symptoms immediately upon arrival. Signs, in appropriate languages, should be posted instructing individuals with fever and respiratory symptoms to alert the staff immediately. These patients should be asked to wear a mask or use tissues to cover their mouth and nose while in the facility. In ambulatory settings, patients who call for an appointment should be asked if they have ILI; this will enable the staff to make arrangements for minimizing exposure of others (e.g., arrival through a separate door directly into an exam room).
- Consider the installation of plexiglass barriers at the point of triage or registration to protect healthcare personnel from contact with respiratory droplets.
- Waiting areas should have information on “Universal Respiratory Protection” or “Respiratory Etiquette.” The waiting areas should have an ample supply of tissues with proper receptacles for disposal. These receptacles should be emptied regularly. The

waiting areas should have hand sanitizers available, disposable towelettes or pump bottles, if hand washing facilities are not available.

- Patients with respiratory illnesses should be kept as far from other patients as possible (at least 3 feet) if they cannot be removed from the common space. Patients reporting ILI should be evaluated as expeditiously as possible. Staff caring for these individuals should wear appropriate personal protective equipment (PPE).
- The use of objects shared by patients, such as pens, pencils and clip-boards, should be evaluated and procedures should be put in place to minimize contamination (disposable pens or pencil, wipes for clipboards).
- Movement of patients with ILI through the facility should be limited. Portable radiographs should be considered. Normal administrative procedures, such as registration, might be altered to restrict patient movement and limit the time in the facility. Standing orders for the basic laboratory evaluation of a suspected influenza case-patient might be created to speed progress through the system.

B. Alternate Emergency Department and Hospital-based Ambulatory Clinic Triage Stations

- Space permitting, facilities could consider having a triage station outside the usual waiting area.
- A standard set of questions should be used to screen patients.
- Patients presenting with ILI would be directed to wait in a room separate from individuals presenting with illnesses thought not to be infectious. Since many of the individuals presenting with ILI will not be diagnosed with influenza, these individuals should be asked to follow the precautions as outlined in “A”.

C. External Emergency Department Triage Stations

This type of measure should be considered only in conjunction with activation of a hospital’s disaster plan.

- The hospital might utilize locations outside the emergency department for triage and evaluation of patients with influenza-like illnesses. These might include, administrative buildings, trailers, etc.
- Those patients with ILI who are stable and thought **not** to need acute care would be directed to another external structure for evaluation. Those patients who present with non-infectious complaints or those with ILI thought to need acute care could be sent to the main building (wearing masks).
- The location used for patient evaluation should have as much diagnostic capability as possible. Considerations should be given to the availability of portable radiography, phlebotomy, pulse oximetry and arterial blood gas assessment. Again, the infection control precautions as outlined in “A” are still appropriate.

Deferred Hospitalization

Hospitals should, in conjunction with their medical staff, develop policies and recommendations for physicians concerning criteria for deferring admissions of patients when the hospital is experiencing a high volume of influenza-related admissions. With scarce hospital resources and

the potential for nosocomial transmission, deferred admissions might be prudent, unless patient care would truly be compromised. Those individuals with solid home supports would be ideal candidates for home management. Hospitals, in conjunction with their medical staff, should encourage development of systems and partnerships in advance, to assure appropriate home management of care.

- Detailed written instructions should be prepared describing what the patient can expect in terms of the clinical course and where to direct questions and concerns.
- Written instructions should stress the importance and methods of maintaining hydration.
- Written instructions should include information (e.g., infection control guidance) for the household care provider on how to best manage the infected individual as well as measures to protect his/her own health and others in the household.
- Partnerships with home health agencies should be encouraged. These agencies would be a valuable resource in caring for patients at home. Home intravenous hydration, antibiotic therapy, oxygen therapy, phlebotomy, placement of intravenous lines and patient assessment would all be valuable services.
- Partnerships with other community providers should be encouraged to ensure that patients receive adequate follow-up and that there is continuity of care.
- Systems for follow-up for those patients who do not have primary care providers should be planned. This may entail the establishment of a follow-up influenza clinic/session at the facility.
- The availability of social services should be ascertained to help coordinate efforts for optimal patient care and safe discharges.
- Partnerships with public health, volunteer organizations, meal delivery services, and mental health providers might be encouraged or strengthened as well.
- “Short stay” outpatient areas within the hospital should be considered for patients to receive hydration, intravenous antibiotics, or monitoring.
- **In the event the hospital’s disaster plan is activated**, use of unlicensed areas outside the main hospital building could be considered for these “short stay” areas discussed above.

Intensive Care

The ability to provide intensive care will likely be the rate-limiting step in a facility’s ability to handle a significant surge in patient volume. It is estimated that, at the peak of a flu epidemic, approximately 21 percent of patients hospitalized with influenza will require care in an intensive care setting. Of those patients, 50 percent will require ventilatory support. In the event of a large surge in patient volume secondary to influenza, intensive care resources, including skilled nursing staff and ventilators, will be stressed. Once again, it is prudent to establish policies and partnerships in advance to deal with the following:

- Developing and/or reviewing policies for cohorting patients.
- Reviewing criteria for admission into and transfer out of the intensive care unit. Given that resources may be stressed, criteria may be considered that differ from those normally in place at the facility.

- Minimizing, to the extent possible, invasive respiratory procedures, such as bronchoscopy and sputum induction. During the SARS outbreak, staff who participated in the performance of invasive respiratory procedures were more likely to have become infected. In one study, greater than 60% of the health care workers affected by SARS had either performed procedures associated with aerosolization of secretions, or were present in the room at the time of the procedures.
- Considering intubation procedures. If intubation is being considered, an effort should be made to do it electively. This will enable the procedure to be performed in a controlled environment with the staff wearing appropriate PPE. Emergent intubation might be associated with more nosocomial transmission.
- Considering the ethical and religious issues involved with the allocation of limited resources. The institution's ethics committee and clergy, along with the clinical staff, will need to play a key role in making difficult decisions expeditiously.
- **If a hospital's disaster plan is activated**, unconventional settings could be utilized to increase intensive care capacity. Ambulatory and inpatient surgery units as well as recovery rooms might be utilized for this purpose.

Facility Planning for Inpatient Care

As mentioned previously, patients should be maintained at home if feasible. Hospital administrators, facility managers, and clinical staff need to complete an assessment of their facilities and devise a plan for dealing with increasing numbers of patients with influenza.

- Influenza patients may be cohorted if the supply of private rooms is exhausted.
- Standing orders for patients with influenza should be considered to expedite transfer from the emergency department to the floor.
- If more than a few patients with influenza are admitted to the facility at a given time, it is prudent to designate a particular area, unit or floor for the care of these individuals. Limiting the geographic area will make it easier to optimize infection control measures and limit the number of staff exposed to the virus. If possible, the area chosen should not be highly trafficked and should not be adjacent to areas where patients at high risk for influenza-associated complications are admitted (e.g., labor and delivery, HIV wards, hemodialysis units, oncology units). The area chosen should have the potential for expansion as patient numbers increase. For instance, patients may be placed on one floor of a particular building in the hospital complex with the expectation that, as patient volume increases, the entire building will be used to cohort influenza patients by adding one floor at a time. Patients without influenza would be cared for in another building of the hospital complex. Obviously, the choice of location will depend on each facility's layout and resources. The plan should not necessitate moving large numbers of influenza-infected patients to a distant site because patient volume has outgrown the originally designated area; relocation of patients would only increase the risk of nosocomial transmission.
- The transportation of patients outside this designated area should be discouraged. Efforts should be made to provide as many clinical services on site as possible (e.g.,

- physical therapy, radiology, PICC line placement). Each patient should be provided with a mask when leaving his/her room.
- Care should be taken to screen **all patients** admitted to other areas of the hospital for influenza symptoms before arriving on the floor or presenting for elective procedures. This would include patients scheduled for elective surgery and women who present in labor. If patient care would not be compromised, patients with ILI should be cared for with other influenza-infected patients. If it is not feasible, strict infection control precautions need to be in place at the site of patient care.
 - Policies to expedite the discharge or appropriate transfer and transport of patients not infected with influenza to alternate care sites should be considered. Discharge planning, social and transportation services should be readily available to the clinical staff on a daily basis to allow for the expeditious and safe transfer and discharge of patients.
 - Identification should be made of alternate space in the hospital that could be used for patient care **after activation of a hospital's disaster plan**. This might include areas not typically used for patient care (administrative offices, conference rooms) as well as external structures, such as trailers. Ambulatory and inpatient surgical suites, endoscopy suites, recovery rooms and day-stay units should become available if elective medical and surgical procedures are cancelled as part of the disaster plan.

Staffing Issues

Human resources are likely to be scarce if there is a large outbreak of influenza. Not only will the volume of patients increase at health care facilities, but staff members might not be able to work because of personal or family illness. Thus, provisions should be made for how best to maintain patient care in the face of scarce human resources.

- The facility's time-off policies and procedures should adequately consider staffing needs during the expected peak influenza season.
- The facility should identify, in advance, staff that might have scheduling difficulty because of child or elder care responsibilities and make appropriate accommodations.
- If possible, staff members caring for patients with ILI should not be used to care for patients without influenza-like illnesses. Rotating staff to different services is more likely to spread influenza throughout the facility.
- The facility's employee health service, in conjunction with management, should play an active role in developing policies during this time. Consider developing procedures to screen employees reporting to work for symptoms of ILI and establishing policies in advance for accepting employees back to work after an ILI. Rapid influenza testing of symptomatic employees may help to make better-informed staffing decisions as well as help to make more effective use of scarce antivirals and vaccine (<http://www.cdc.gov/flu/professionals/treatment>). When the employee health service determines a staff member is symptomatic with influenza, that individual should be sent and remain home until afebrile (T

<100.5) and symptomatically improved. Employees who meet criteria for pneumococcal vaccine should be encouraged to be vaccinated.

- The facility should consider using clinically trained administrative staff not usually engaged in patient care services. Consider “refresher courses” in advance for these staff members and be sure to comply with licensure standards regarding qualifications and orientation.
- Staff should be advised to maintain personal care kits, including necessary personal items and medications, in the event there is an unforeseen emergent circumstance that requires them stay beyond a scheduled shift. Note that rules limiting the imposition of mandatory overtime will not be relaxed unless the situation clearly qualifies as one of the exceptions provided for under the law governing mandatory overtime.
- **In the event that the hospital’s disaster plan has been activated,** the facility should consider identifying a family member or friend of each inpatient to help with personal care of the patient, thus alleviating the need for hospital personnel to perform non-medical duties. These individuals must receive instruction in and practice infection control precautions.

Nosocomial Transmission

If an outbreak of influenza occurs, transmission within the facility is more likely to occur because of the large number of persons (patients, staff and visitors) who will be infected. There may be difficulties implementing optimal infection control practices due to increased patient loads, staff shortages, and use of non-routine or volunteer staff. Active surveillance for nosocomial influenza infection needs to be implemented by the initiation of enhanced infection control measures.

- Implementation of surveillance for nosocomial onset of acute febrile respiratory illness or pneumonia (onset \geq 48 hours after admission). The former would include documenting new onset of fever $>$ 100.5 F, with or without myalgia, malaise, or headache and with one or more of the following symptoms: sore throat, cough, rhinorrhea, or nasal congestion. When a suspect case or cluster of cases is identified, obtain specimens for viral testing. Rapid testing should be considered for more expeditious diagnosis.
- Investigation by infection control personnel to identify potential causes of the outbreak or factors that contribute to ongoing spread. These investigations might identify a specific area of the facility that is the focus, determine whether infected health care workers might be transmitting the virus, and assess how well infection control practices are being implemented.
- Control measures should be implemented. These might include cohorting patients, educating staff members, placing staff on leave or changing their patient-care responsibilities, and use of vaccine or antiviral prophylaxis, if available.
- Communicating with the local health department for assistance with coordination. Patients might need to be diverted to other facilities until the internal chain of transmission is broken.

Other Issues

- The facility should ensure that adequate security is available to handle high volumes of patients in the emergency department
- The facility should redouble efforts to ensure compliance with licensure standards requiring that all patients age 65 and over shall be screened and, if eligible, offered vaccination against pneumococcal disease. Providers in ambulatory settings could review the guidelines for pneumococcal vaccine and offer vaccine to high-risk individuals (<http://www.cdc.gov/mmwr/PDF/rr/rr4608.pdf>).
- The facility might need to request additional supplies (ventilators, intubation equipment, intravenous catheters, intravenous pumps) from new sources. These supplies may not be those normally used in the facility and might have to bypass normal committee and clinical engineering review. The hospital should make arrangements in advance for the use of these supplies.
- The facility should partner with community providers. Patients with identified primary care physicians should be encouraged to contact their provider prior to presenting to an acute care facility. Primary care providers should make every effort to accommodate patients; physician groups might consider providing extended evening or weekend hours to alleviate the volume at acute care facilities.
- The facility should ensure that the staff, patients, and visitors receive accurate information; the information should be consistent with the messages from local and state health agencies.
- Mental health providers should be available to help patients and staff deal with heightened stress and anxiety levels.
- Facilities should review policies regarding ambulance diversion. Ambulance diversion is a response to overcrowding that should be used sparingly; it is an advisory status, not a mandate. In the event of a surge in patient volume as a result of influenza, all hospitals in the region are likely to be experiencing similar stresses; therefore, diversion will only place a greater stress on the overall health care delivery system.

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APPENDIX C

TROUTMAN SANDERS, LLP. *SHARING
INFORMATION DURING DISASTERS: HIPAA
IMPLICATIONS, APRIL 2007*



Sharing Information During Disasters: HIPAA Implications

**Prepared by:
Steve Gravely, J.D., M.H.A.
Erin Whaley, J.D., M.A.
Troutman Sanders LLP**

**Prepared for:
Virginia Hospital and Healthcare Association**

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Introduction

Preparations for mass casualty events, including an influenza pandemic, have caused health care providers to question whether the privacy protections of the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) will inhibit their ability to respond. While health care providers will need to share PHI with other entities during any large scale disaster or emergency for various reasons, this need will be particularly important in a public health emergency. Hospitals must understand the contours and nuances of their responsibilities under HIPAA during disasters as well as ways in which they can protect themselves from liability for potentially unavoidable violations. For instance, there are a variety of emerging initiatives such as patient tracking, absence reporting, and employee screening programs, which are being developed to enhance health care providers’ responses to disasters. While none of these initiatives are expressly prohibited by HIPAA, consideration must be given to protecting the PHI that may be used and disclosed with these initiatives.

To help answer these questions, the Virginia Hospital and Healthcare Association engaged Troutman Sanders LLP to analyze the current state of HIPAA law with respect to disasters and draft this white paper for all Virginia hospitals. This paper focuses generally on those disclosures permitted by HIPAA which will be most relevant during disasters: (1) for treatment, payment and operations; (2) required by law; (3) for public health activities; (4) to avert a serious threat to health or safety; (5) for national security and intelligence activities, and; (6) to notify those involved in the individual’s health care.¹

The results of this analysis are mixed. The good news is that, during an emergency or disaster, there are numerous regulatory exceptions to HIPAA that will permit hospitals to share protected health information with other providers, public health authorities and certain other

designated parties. The bad news is that, even during a disaster, the majority of HIPAA requirements will remain in effect so hospitals must plan as if they will be responsible for fulfilling all HIPAA obligations even in the midst of a disaster.

I. Overview of HIPAA

Passed by Congress in 1996, HIPAA created a new “civil right” for the protection of personally identifiable health information.² The Privacy provisions of HIPAA were significantly delayed in their implementation and the final Privacy Rule was not effective until 2001.³ Once effective, HIPAA imposed sweeping new restrictions on how PHI is used and disclosed by covered entities. In anticipation of the Privacy Rules becoming final, health care providers implemented comprehensive new policies and procedures to comply with HIPAA and spent countless hours educating their staff on HIPAA requirements. There were widespread concerns that HIPAA would prevent hospitals from functioning and that the burden of HIPAA compliance would inhibit the delivery of care. These concerns have not materialized in terms of the daily operation of health care facilities, but still exist when contemplating a hospital’s response to a wide scale emergency or disaster. While extensive guidance has been issued in recent years clarifying HIPAA’s privacy rules in both everyday and disaster circumstances, HIPAA compliance remains an extremely important and often complex issue for health care providers.

At its core, HIPAA regulates the use and disclosure of “protected health information” (PHI) by “covered entities,” which includes hospitals and other health care providers. Protected Health Information is very broadly defined to include all individually identifiable health information that relates to a past, present or future physical or mental health condition of an individual, the provision of health care to an individual, or payment for care.⁴ For HIPAA

purposes, “use” generally refers to the ways in which PHI is used within a HIPAA Covered Entity. “Disclosure” refers to the sharing of PHI by a Covered Entity with others.

“A central aspect of the Privacy Rule is the principle of “minimum necessary” use and disclosure. A covered entity must make reasonable efforts to use, disclose, and request only the minimum amount of protected health information needed to accomplish the intended purpose of the use, disclosure, or request.”⁵ Whether or not the “minimum necessary” standard applies to a given use or disclosure is a function of the regulatory requirements surrounding that use or disclosure. Applicability of the standard will be discussed in the context of each permissive use discussed in this paper.

In addition to abiding by the “minimum necessary” rule when applicable, patient consent or authorization is required for virtually all uses and disclosures of PHI. “Consent” under HIPAA requires that the patient be informed of his privacy rights through a Notice of Privacy Practices and be allowed to set some limitations on how his PHI can be shared. Fortunately for health care providers, HIPAA does allow for consents to be rather generally worded to cover all uses and disclosures related to treatment, payment and health care operations, and to remain in effect until revoked. These general consents allow providers to use and disclose a patient’s PHI, as necessary and subject to other HIPAA restraints, without having to obtain additional consents from the patient. These consent provisions have been incorporated into hospital operations.

A covered entity must obtain the individual’s written “authorization” for any use or disclosure of protected health information that is not for treatment, payment or health care operations or otherwise permitted or required by the Privacy Rule.⁶ “Authorization” under HIPAA is very different from “consent.” As opposed to the general nature of consents, in an authorization, a patient gives permission for the covered entity to use or disclosure his PHI for a

certain purpose or limited event. Such authorizations must be treated as part of the medical record and the covered entity must keep a record of the information that was disclosed pursuant to the authorization.

Outside of this framework, “[t]he Privacy Rule permits use and disclosure of protected health information, without an individual’s authorization or permission, for 12 national priority purposes.⁷ These disclosures are permitted, although not required, by the Rule in recognition of the important uses made of health information outside of the health care context. Specific conditions or limitations apply to each public interest purpose, striking the balance between the individual privacy interest and the public interest need for this information.”⁸ It is a subset of these 12 national priority purposes that will be the focus of this paper as, outside of treatment, they will be the most relevant to information sharing during a disaster.

It is important for covered entities to understand the nuances, contours and requirements of HIPAA because failure to comply can result in investigations and penalties. HIPAA enforcement is a compliant driven process that is managed by the Office of Civil Rights (“OCR”). OCR does not initiate investigations of a covered entity’s compliance absent a complaint. OCR has stated that it will make every effort to counsel providers on how to improve compliance with HIPAA provisions. This has provided some reassurance that enforcement will be even-handed and conducted in a way to help effective compliance by the covered entity. However, responding to a HIPAA complaint can be extremely time consuming and difficult. In addition to the stress associated with the investigation of a HIPAA complaint, if a violation is found, the covered entity can be subjected to civil and/or criminal penalties depending on the facts surrounding the violation.⁹

III. **OCR Tool for Sharing PHI During Disasters**

The U.S. Department of Health and Human Services Office of Civil Rights (“OCR”) recently issued a HIPAA emergency planning tool.¹⁰ This tool, which is essentially a flowchart that healthcare providers can use to determine whether they are permitted to share information during a public health emergency, was designed to yield quick answers for the provider. “The tool focuses on the source of the information being disclosed, to whom the information is being disclosed, and the purposes of the information being disclosed.”¹¹ While this tool can yield rapid answers, it cannot answer the complicated, nuanced HIPAA questions that hospitals will likely have during a public health emergency. Hospitals must still have a thorough understanding of HIPAA’s requirements and exceptions in relation to emergencies and disasters.

*The OCR HIPAA
decision tool is
available at
<http://www.hhs.gov/ocr/hipaa/decisiontool>.*

IV. **Treatment, Payment or Health Care Operations**

In all situations, including emergencies and disasters, health care providers are allowed to share protected health information (“PHI”) as necessary to carry out treatment, payment or health care operations.¹² With the patient consents that health care providers routinely obtain, as described in the Hurricane Katrina Bulletin issued on September 2, 2005 by the Department of Health and Human Services Office for Civil Rights (“Bulletin #1”), treatment includes:

- Sharing information with other providers (including hospitals and clinics),
- Referring patients for treatment (including linking patients with available providers in areas where the patients have relocated), and
- Coordinating patient care with others (such as emergency relief workers or others that can help in finding patients appropriate health services).

This Bulletin #1 excerpt reflects the fact that, especially during a disaster, OCR will take a fairly broad view of “treatment,” which should facilitate the prompt sharing of PHI during emergencies.

Where a covered entity is disclosing PHI to another health care provider for treatment purposes, the “minimum necessary” standard does not apply.¹³ Where the disclosure is to

When sharing PHI for treatment, “minimum necessary” does not apply.

another person or agency that will use or disclose the information for treatment, however, the minimum necessary standard does apply.¹⁴ For instance, when a hospital discloses PHI to a third party organization that will coordinate patient care, the hospital may only disclose the minimum necessary amount of PHI to accomplish the

coordination. Additionally, when disclosures are made for treatment purposes, the accounting requirements are inapplicable because these disclosures are covered by the patient’s initial consent.¹⁵

V. Disclosures Not Related to TPO

Beyond disclosures for payment, treatment and operations, HIPAA does contain strict prohibitions on the disclosure of PHI. However, it also contains numerous exceptions that allow covered entities to share such information without an individual’s consent. These exceptions, where applicable, do not turn on the presence or absence of emergency or disaster. Instead, each exception has its own criteria which must be met before it can be

Outside of TPO, when an exception applies, PHI can be disclosed without consent.

used to justify a disclosure without consent. Only those exceptions which may be most relevant during emergencies and disasters are examined, in this paper, specifically those disclosures that are: (1) required by law; (2) for public health activities; (3) to avert a serious threat to health or

safety; (4) for national security and intelligence activities, and; (5) to notify those involved in the individual's health care.¹⁶

Required by Law

The HIPAA Privacy Rule allows health care providers to disclose PHI to the extent that such disclosure is required by law.¹⁷ While there are many instances in which a covered entity will be required to disclose PHI to be compliant with laws (i.e. responding to a subpoena, reporting child abuse), this is a particularly important exception in the communicable disease context. Each state, including Virginia, has a list of "reportable diseases," those diseases which must be reported by health care providers to local health departments. Importantly, according to Virginia's Reportable Disease List, the following diseases must be reported within 24 hours of suspected or confirmed diagnosis by the most rapid means available:

- Disease caused by an agent that may have been used as a weapon;
- All outbreaks;
- Severe Acute Respiratory Syndrome; and
- Unusual occurrence of disease of public health concern.¹⁸

In addition to these broad categories of diseases which must be reported to the state within 24 hours of suspected or confirmed diagnosis, cases of influenza must be reported to the state within three days of suspected or confirmed diagnosis by

*In Virginia,
influenza is a
reportable
disease.*

laboratory directors, physicians and medical care facility directors.¹⁹ Providers are asked to report the aggregate number of influenza cases each week and the type of influenza if known. Taken together, the list of reportable diseases in Virginia should be broad enough to trigger the

“required by law” exception thus enabling hospitals to report any diseases that might lead to a public health emergency.

While the minimum necessary standard is not applicable to disclosures that are required by law,²⁰ covered entities are advised to limit disclosures to the PHI “necessary to meet the requirements of the law that compels the disclosures.”²¹ Further, when an individual requests an accounting, disclosures made as required by law must be listed.

Public Health Activities

The HIPAA Privacy Rule permits health care providers to disclose PHI to certain recipients for public health activities.²² Under this exception, covered entities may disclose PHI to “public health authorities” for certain enumerated purposes. The HIPAA regulations define “public health authorities” as (i) those agencies of the federal or state government that are responsible for public health matters as a part of its official mandate; or (ii) any person or entity “acting under a grant of authority from or contract with such” agency.²³

A covered entity may disclose PHI to a “public health authority that is authorized by law²⁴ to collect or receive such information for the purpose of preventing or controlling disease,

A covered entity may disclose PHI to a public health authority for:

- ◆ *Surveillance*
- ◆ *Investigations*
- ◆ *Interventions*

injury or disability, including, but not limited to, the reporting of disease ... and the conduct of public health surveillance, public health investigations and public health interventions.”²⁵

Examples of public health authorities covered by this HIPAA provision include local health departments, state public health agencies and federal public health agencies, such as the Centers for Disease Control and Prevention.²⁶ This exception, therefore, gives health care providers the ability to report

communicable disease incidences to local or state health departments so that they may begin or continue surveillance, investigations or interventions.

It is not clear whether this exception gives covered entities the ability to report PHI to Regional Hospital Coordinating Centers (“RHCC”), local Emergency Operations Centers (“EOC”) or the Medical Control Officer (“MCO”) for surveillance, investigations or interventions. While these three bodies will play an important role in emergency and disaster preparedness and response, it is not clear that they are “authorized by law” to conduct the enumerated public health activities. Unless there is a statute, regulation, or ordinance authorizing such activities, covered entities probably should not rely on the HIPAA public health activity exception to report PHI to the RHCC, EOC or MCO.

It is not clear that RHCCs, EOCs, and MCOs qualify for the public health exception.

If the public health activities exception does apply, hospitals must remember that they are only able to make disclosures to public health authorities subject to the minimum necessary standards.²⁷ Covered entities may reasonably rely on a public official's request as constituting minimum necessary for the stated purpose if the public official states that the information requested is the minimum necessary to accomplish the activity.²⁸

A covered entity may also notify individuals who may have been exposed to a communicable disease or who might be at risk of contracting or spreading a disease, when authorized by law in the course of a public health intervention or investigation.²⁹

If informing a person of a potential exposure, do not inform him of the source of the exposure.

Importantly, this exception does not give a covered entity *carte blanche* with respect to informing individuals that they may have been exposed to a communicable disease. The entity may so inform the individual, but not reveal another individual’s PHI unless *authorized by law in*

the course of the public health investigation. To date, there are no laws in Virginia that authorize a health care provider to make such a disclosure. When informing an individual that he may have been exposed to a communicable disease, therefore, inform him of the potential exposure, the disease in question (if known) and any suggested follow-up care. A health care provider should not reveal the identity of the individual responsible for the exposure unless it has the individual's authorization to do so.

Because employers are understandably concerned about the health and safety of their workforce, covered entities may disclose an employee's PHI to an employer under certain conditions. To qualify for the exception, five criteria must be met:

1. The health care provider provides care to an individual at the request of the employer or the provider is a member of the employer's workforce;
2. The care is being provided to conduct medical surveillance of the workplace or to evaluate work-related illness or injury;
3. The PHI to be disclosed consists of findings concerning work-related illness or injury or a workplace-related medical surveillance;
4. The employer needs such findings to comply with the Occupational Safety and Health Administration Act ("OSHA") or the Mine Safety and Health Administration Act ("MSHA"); and
5. The covered provider gives the employee (patient) written notice that PHI will be disclosed to the employer.³⁰

In most cases, the limiting factor will be criteria #4, whether the employer needs such findings to comply with OSHA or MSHA. Under the OSHA "general duty clause," employers

OSHA "General Duty" Clause requires employers to provide a workplace free from hazards.

have a duty to provide their employees with a workplace free from recognized hazards likely to cause death or serious physical harm.³¹

Employers have come to appreciate that this means taking certain precautions to help prevent employees from coming in contact with biological hazards, including a pandemic influenza virus, while at

work. As part of employers' pandemic preparedness plans, many are considering instituting medical surveillance to quickly identify and contain those employees who have been in contact with the pandemic virus or who are beginning to exhibit symptoms. PHI obtained through this surveillance can likely be released to the employer if the other four requirements are met.

Outside of a pandemic surveillance context, to comply with OSHA, employers must record all new cases of work-related fatalities, injuries, and illnesses if they involve a number of things, including days away from work, medical treatment, a significant injury or illness diagnosed by a physician, or death.³² Because most communicable diseases will result in one of these responses, if an employee was infected with a communicable disease through work-related activities, the provider rendered treatment at the request of the employer and the other criteria are satisfied, PHI related to the illness can be disclosed to the employer.

Individuals have a right to receive an accounting of all disclosures of PHI made for public health activities.³³ This means that when a covered entity makes a disclosure for public health activities, it must record the date of the disclosure, the name of the entity or person who received the information, the address of the

Providers must include disclosures for public health activities in an accounting.

recipient if known, a brief description of the information disclosed, and a brief statement of the purpose of the disclosure.³⁴ Importantly, this accounting requirement has not been waived in any of the guidance on emergency preparedness and response in relation to HIPAA.

Recognizing that public health authorities may request PHI on a large number of individuals, DHHS has clarified that the Privacy Rule does not require a notation in each medical record that has been accessed by public health authorities.³⁵ The covered entity need only document the identity (and address if known) of the public health authority to which access was

provided, a description of the records and PHI subject to access, the purpose for the disclosure, and when access was provided. This information should be provided to an individual who requests an accounting if the individual's PHI was within the universe of disclosed records.

Disclosure of PHI is permitted to abate a serious or imminent threat to the public.

DHHS provides the following example: On August 1, 2003, a hospital began providing a public health authority ongoing access to the medical records of all patients treated in the hospital emergency department to identify reportable cases and extract relevant information required for a particular surveillance activity. It would satisfy the HIPAA Privacy Rule to include the following in the accounting:

- the identity and address, if known, of the public health authority;
- a statement that the public health authority had access to medical records for patients treated in its emergency department;
- the date (or approximate range of dates) when the individual's record was subject to access; and
- a statement of the purpose of the access (i.e., identification of the particular public health surveillance activity).³⁶

The same basic statement could then be provided in response to a request for an accounting by any individual who was seen in the ED on or after August 1, 2003.³⁷

Averting a Threat to Health or Safety

A covered entity may disclose PHI without patient consent to prevent or lessen a serious and imminent threat to the health or safety of a person or the public.³⁸ Disclosure of PHI in such a situation must be to a person or persons reasonably able to abate the threat.³⁹ For example, when a provider identifies an unexplained disease outbreak suspected to be the result of a bioterrorist attack, the provider may disclose PHI of infected individuals to certain public officials to control the outbreak and prevent further infection.⁴⁰ Such disclosures must also comply with the minimum necessary standard⁴¹ and accounting requirements.⁴²

Importantly, the Privacy Rule imparts a good faith requirement on the provider disclosing the PHI.⁴³ There is a presumption that the provider has acted in good faith if its belief in the threat to health or safety is based on actual knowledge or reliance on credible representation by a person with apparent knowledge or authority.⁴⁴ The presumption of good faith may shield a provider from liability if a disclosure is made but, in fact, no threat to health or safety is found to exist. In order to overcome the good faith presumption, it would be necessary to prove that the

There are various exceptions related to notifications.

disclosing provider did not base its belief in the threat on actual knowledge or reasonable reliance on a person with apparent knowledge or authority.

National Security

Under the HIPAA Privacy Rule, a provider may disclose PHI without patient consent to authorized federal officials for the conduct of lawful intelligence, counter-intelligence and other national security activities authorized by the National Security Act.⁴⁵ This exception may be applicable in a bioterrorist attack situation and would allow providers to disclose PHI to government authorities in the course of their investigation of bioterrorism. While covered entities should keep records on disclosures made pursuant to this exception, individuals do not have a right to receive an accounting of these disclosures.⁴⁶

Notification

In a disaster or emergency, health care providers may disclose the minimum necessary PHI to identify, locate and notify family members, guardians or anyone else responsible for the care of the individual, of the individual's location, general condition or death.⁴⁷ Disclosure may be made directly to those involved in the individual's care, the police, the press, the public at large, or to a public or private entity authorized by law or its charter to assist in disaster relief

efforts, such as the American Red Cross.⁴⁸ Whenever possible, verbal permission to disclose PHI should be obtained from the individual receiving care, but if the person is incapacitated, not available or the permission cannot practicably be provided because of the emergency circumstances, providers may disclose PHI if, in their professional judgment, doing so is in the patient's best interest.⁴⁹ Additionally, if obtaining a patient's consent to release information to a disaster relief organization would interfere with the organization's ability to respond to the emergency, such consent is unnecessary.⁵⁰

Similarly, covered entities may use a patient's name, location in the facility, and information about his general condition in the facility directory.⁵¹ While individuals are usually given the opportunity to opt-out of inclusion in the directory, when emergency circumstances make the opportunity to opt-out impractical, such opportunity does not have to be provided.⁵² The individual's information can then be included in the directory if the health care provider determines that it is consistent with the patient's prior expressed preferences (if known) and in the patient's best interest.⁵³

When a facility makes a disclosure for notification purposes or in the facility directory, it is not bound by the accounting requirements.⁵⁴ In other words, the facility does not have to record instances in which PHI is disclosed for notification or in the facility directory.

Hospitals can have a facility directory that includes:

- ◆ *Patient's name*
- ◆ *Location in facility*
- ◆ *General condition*

VI. Section 1135 Waiver

Congress has recognized that, in certain situations, enforcement of HIPAA requirements will need to be waived. In 2002, Congress enacted the Public Health Security and Bioterrorism

Response Act, which added a Section 1135 to the Social Security Act. Upon a Presidential declaration of emergency or disaster pursuant to the Stafford Act⁵⁵ or a Secretarial declaration of public health emergency pursuant to the Public Health Service Act⁵⁶, Section 1135 authorizes the Secretary of HHS to “temporarily waive or modify the application of” certain Medicare, Medicaid and SCHIP requirements to the extent necessary to exempt healthcare providers from sanctions when emergency circumstances have left them unable to comply with such requirements.⁵⁷ Included in the list of requirements for which sanctions can be waived are selected HIPAA requirements.

Specifically, the Secretary can waive sanctions and penalties that arise from noncompliance with the following HIPAA requirements:

- to obtain a patient’s agreement to speak with family members or friend;
- to honor a request to opt out of the facility directory;
- to distribute a notice of privacy practices; and
- to provide patients with a right to request privacy restrictions or confidential communications.

Waivers are generally limited to the 72-hour period beginning upon implementation of a hospital disaster protocol unless the Waiver arises out of a public health emergency involving a pandemic.⁵⁸ If related to a pandemic, the Waiver terminates upon the first to occur of either the termination of the underlying declaration of a public health emergency or 60 days after being first published.⁵⁹ If the waiver terminates because of the latter, the Secretary may extend it for subsequent 60 day periods.⁶⁰

As alluded to above, the Secretary can only issue this Section 1135 Waiver for health care services rendered during an “emergency period” in an “emergency area.” The statute

defines “emergency area” and “emergency period” as the geographical area and period (respectively) in which there is a presidentially declared disaster or emergency under the Stafford Act⁶¹ or a public health emergency as declared by the Secretary under the Public Health Service Act.⁶² This means that Section 1135 waivers will not be available for local and state declared emergencies and disasters for which there is no presidential declaration.⁶³

Section 1135 Waivers are not available for local and state emergencies.

In the wake of the Presidential declaration of emergency in Louisiana and surrounding states for Hurricane Katrina in August 2005,⁶⁴ the Secretary of HHS issued a Section 1135 Waiver related to various statutes and regulations, HIPAA. The Secretary’s Section 1135

The HIPAA Waiver issued post-Katrina was only effective for 72 hours.

Waiver exempted hospitals from sanctions for noncompliance only in the four categories listed at the beginning of this section. This means that hospitals were still required to comply with the majority of HIPAA requirements. Furthermore, this Waiver was only effective for 72 hours after hospitals implemented their hospital disaster protocols, as required by the Section 1135 statute.⁶⁵ After this 72 hour mark, hospitals had to comply with all HIPAA obligations or risk penalties for noncompliance.

VII. HIPAA Guidance Issued Post Hurricanes Katrina and Rita: Business Associates and Business Associate Agreements

A bulletin issued by OCR following Hurricane Katrina provided guidance to covered entities with respect to disclosures to business associates.⁶⁶ In general, a health care provider may disclose PHI to a business associate only to the extent permitted in the business associate agreement. There may be instances during an emergency or disaster when needed disclosure of PHI is not within the parameters of the business associate agreement. The provider and business

associate may amend the agreement to allow for such disclosure. Where time and circumstances prohibit a formal amendment, however, providers and business associates should proceed with the necessary disclosure and amend the agreement as soon as practicable.

Providers should be aware that this specific DHHS waiver of HIPAA liability was posted only in response to Hurricane Katrina, and it cannot be assumed that the same such waiver will apply in future emergency or disaster situations.

BAAs should be amended to provide for disclosures during a disaster.

Health care providers are well-advised to review (and amend, where appropriate) their existing business associate agreements to account for disclosures that may be necessitated by a disaster or emergency.

VIII. Conclusion

There are significant exceptions to HIPAA's stringent Privacy Rule that will allow covered entities to share PHI during emergency and disaster situations, including communicable disease outbreaks. To the extent a hospital's HIPAA policies and procedures do not reflect these exceptions, they should be amended. Hospitals may also consider creating a separate set of HIPAA policies that will only apply during emergency and disaster situations. Regardless of how a hospital chooses to incorporate the HIPAA exceptions discussed in this paper, employees, staff and providers should be educated on these issues so that their ability to share information is not unnecessarily impeded during a disaster.

Notes

¹ See U.S. Department of Health and Human Services Office for Civil Right, “Hurricane Katrina Bulletin: HIPAA Privacy and Disclosures in Emergency Situation,” September 2, 2005 (Bulletin #1) for a brief overview of permissible disclosures of PHI in emergency situations.

² Pub. L. 104-191

³ The final Privacy Rule became effective April 14, 2001 with compliance required by April 14, 2003. See <http://www.hhs.gov/ocr/hipaa/bkgrnd.html> for more information.

⁴ 45 C.F.R. § 160.103

⁵ 45 C.F.R. § § 164.502(b) and 164.514(d).

⁶ 45 C.F.R. § 164.508.

⁷ See 45 C.F.R. § 164.512.

⁸ OCR Privacy Brief, “Summary of the HIPAA Privacy Rule,” available at <http://www.hhs.gov/ocr/privacysummary.pdf> (last visited March 23, 2007) (the “OCR Summary”).

⁹ “HHS may impose civil money penalties on a covered entity of \$100 per failure to comply with a Privacy Rule requirement. Pub. L. 104-191; 42 U.S.C. § 1320d-5 That penalty may not exceed \$25,000 per year for multiple violations of the identical Privacy Rule requirement in a calendar year. HHS may not impose a civil money penalty under specific circumstances, such as when a violation is due to reasonable cause and did not involve willful neglect and the covered entity corrected the violation within 30 days of when it knew or should have known of the violation.

“A person who knowingly obtains or discloses individually identifiable health information in violation of HIPAA faces a fine of \$50,000 and up to one-year imprisonment. Pub. L. 104-191; 42 U.S.C. § 1320d-6. The criminal penalties increase to \$100,000 and up to five years imprisonment if the wrongful conduct involves false pretenses, and to \$250,000 and up to ten years imprisonment if the wrongful conduct involves the intent to sell, transfer, or use individually identifiable health information for commercial advantage, personal gain, or malicious harm. Criminal sanctions will be enforced by the Department of Justice.” The OCR Summary.

¹⁰ See U.S. Department of Health and Human Services Office for Civil Rights, “HIPAA Privacy Rule: Disclosures for Emergency Preparedness – A Decision Tool,” available at <http://www.hhs.gov/ocr/hipaa/decisiontool> (last visited August 15, 2006) (the “OCR Tool”).

¹¹ See the OCR Tool.

¹² 45 CFR §§ 164.502(a)(1)(ii) and 164.506(c).

¹³ See 45 CFR § § 164.502(b)(1)(i) and 164.514(d).

¹⁴ 45 CFR § 164.502(b)(1). See also the OCR Tool.

¹⁵ 45 CFR § 164.528(a)(1)(i).

¹⁶ See U.S. Department of Health and Human Services Office for Civil Right, “Hurricane Katrina Bulletin: HIPAA Privacy and Disclosures in Emergency Situation,” September 2, 2005 (Bulletin #1) for a brief overview of permissible disclosures of PHI in emergency situations.

¹⁷ 45 CFR § 164.512(a).

¹⁸ This is not a comprehensive list of the diseases included on the Virginia Reportable Disease List. For the full list see Virginia Reportable Disease List available at www.vdh.state.va.us/epi/list.asp (last visited August 15, 2006).

¹⁹ Id.

²⁰ 45 CFR § 164.502(b)(2)(iv).

²¹ 65 FR 82525 (December 28, 2000).

²² 45 CFR § 164.512(b).

²³ 45 CFR § 164.501.

²⁴ In Virginia, the Commissioner of the Department of Health or his designee is authorized by law to “examine and review any medical records ... in the course of investigation, research or studies of diseases or deaths of public health importance.” Va. Code Ann § 32.1-40. “Diseases of public health importance” is not a defined term in the Code; therefore, it is unclear under exactly what circumstances the Commissioner can review records. The statute does, however, state that “[n]o such practitioner or person shall be liable in any action at law for permitting such examination and review.” Based on this, hospitals should share PHI with the Commissioner, or his designee, when requested for purposes of investigation, research or studies.

²⁵ 45 CFR § 164.512(b)(1)(i).

²⁶ See OCR Tool.

²⁷ See 45 CFR § § 164.502(b) and 164.514(d).

²⁸ See 45 CFR § 164.514(d)(3)(iii)(A) and the OCR Tool.

²⁹ 45 CFR § 164.512(b)(1)(iv).

³⁰ 45 CFR § 164.512(b)(1)(v).

³¹ See Section 5(a)(1) of the Occupational Safety and Health Act (29 U.S.C. § 654).

³² 29 CFR § 1904 et seq.

³³ 45 CFR § 164.528(a).

³⁴ 45 CFR § 164.528(b).

³⁵ See <http://www.hhs.gov/hipaafaq/permitted/research/465.html>, Answer ID 465 (last visited April 23, 2007).

³⁶ *Id.*

³⁷ *Id.*

³⁸ 45 CFR § 164.512(j). This provision in the HIPAA Privacy Rule is consistent with Virginia law (see Va. Code §§ 32.1-127.1:03(D)(6), 32.1-127.1:04).

³⁹ 45 CFR § 164.512(j)(1)(i)(B).

⁴⁰ This course of action may also fall under the public health activities exception.

⁴¹ See 45 CFR § § 164.502(b) and 164.514(d).

⁴² See 45 CFR § 164.528.

⁴³ 45 CFR § 164.528(j)(4)

⁴⁴ 45 CFR § 164.512(j)(4).

⁴⁵ 45 CFR § 164.512(k)(2); see also 50 U.S.C. § 401 et seq.

⁴⁶ 45 CFR § 164.528(a)(1)(iv).

⁴⁷ 45 CFR § 164.510(b).

⁴⁸ See Bulletin #1.

⁴⁹ 45 CFR § 164.510(b)(3).

⁵⁰ See Bulletin #1 and 45 CFR § 164.510(b)(4).

⁵¹ 45 CFR § 164.510(a).

⁵² 45 CFR § 164.510(a)(3).

⁵³ 45 CFR § 164.510(a)(3).

⁵⁴ 45 CFR § 164.528(a)(1)(iii).

⁵⁵ The Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121-5206 (the “Stafford Act”), was created to “provide an orderly and continuing means of assistance by the Federal Government to State and local government in carrying out their responsibilities to alleviate the suffering and damage which result from disasters.”(42 U.S.C. § 5121(b)) To accomplish this lofty goal, the Stafford Act establishes a process for requesting and obtaining a Presidential disaster declaration, defines the type and scope of assistance available from the Federal government, and describes the conditions for obtaining that assistance. The Stafford Act requires that “all requests for a declaration by the President that a major disaster exists shall be made by the Governor of the affected State.”(42 U.S.C. § 5170) The Governor must make his request through the regional Federal Emergency Management Agency (“FEMA”) office and take appropriate action to execute the state’s emergency plan. (See *A Guide to the Disaster Declaration Process and Federal Disaster Assistance*, Federal Emergency Management Agency, available at http://www.fema.gov/pdf/rebuild/recover/dec_proc.pdf (last visited December 5, 2006). The Governor’s request must include information on the nature and amount of state and local resources that have been or will be committed to alleviating the disaster, an estimate on the amount and severity of damage caused by the disaster, and an estimate of the amount of federal assistance that will be needed. Based on the Governor’s request, the President may declare that a major disaster or emergency exists or deny the request.(Id.)

⁵⁶ Section 319(a) of the Public Health Service (PHS) Act, authorizes the Secretary of the Department of Health and Human Services (HHS) to declare a public health emergency and “take such action as may be appropriate to respond” to that emergency consistent with existing authorities. (42 U.S.C. § 247d.) The Secretary may declare a public health emergency when, after consultation with public health officials, he finds that “a disease or disorder presents a public health emergency or a public health emergency, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists.”(42 U.S.C. § 247d(a))

⁵⁷ 42 U.S.C. § 1320b-5(a)(2).

⁵⁸ 42 U.S.C. § 1320b-5(b). The EMTALA TAG is recommending that the 72-hour limitation be extended to allow the waiver to remain in effect until the hospital is no longer in an emergency situation or the government-declared emergency has been terminated. See note 23.

⁵⁹ 42 U.S.C. § 1320b-5(e).

⁶⁰ Id.

⁶¹ Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121-5206.

⁶² Id. and the Public Health Service Act, 42 U.S.C. § 201 et seq.

⁶³ The EMTALA TAG recently recommended that Section 1135 Waivers be expanded to provide protections to include declared state, county and city emergencies as well as hospital-specific emergencies as determined by CMS/OIG on a case-by-case basis. See note 23.

⁶⁴ See Statement on Federal Emergency Assistance for Louisiana issued The White House, August 27, 2005, available at <http://www.whitehouse.gov/news/releases/2005/08/20050827-1.html> (last visited December 5, 2006).

⁶⁵ 42 U.S.C. 1320b-5(b)(3).

⁶⁶ See U.S. Department of Health and Human Services Office for Civil Right, “Hurricane Katrina Bulletin #2: HIPAA Privacy Rule Compliance Guidance and Enforcement Statement for Activities in Response to Hurricane Katrina,” September 9, 2005.

APPENDIX D

TROUTMAN SANDERS, LLP. *EMTALA*
COMPLIANCE IN DISASTER
CIRCUMSTANCES. MARCH 2007



***EMTALA Compliance
In
Disaster Circumstances***

**Prepared by:
Steve Gravely, J.D., M.H.A.
Erin Whaley, J.D., M.A.
Troutman Sanders LLP**

**Prepared for:
Virginia Hospital and Healthcare Association**

March 2, 2007

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I. Introduction

There are reports that during Hurricanes Katrina and Rita, “hospitals simply turned away people with minor medical problems because they had been inundated with large numbers of patients with major injuries and illnesses.”¹ Despite all of the focus on “surge capacity,” there is increasing recognition that hospitals simply will not have the ability to treat all comers when faced with a rapid influx of patients from a mass casualty event such as a natural disaster, terrorist attack or public health emergency. Hospitals will have to choose which patients will be treated and which will not. It is this decision, the decision to turn away patients with minor ailments, that causes hospitals to cringe both because denying care violates a fundamental tenet of the American health care system and because it potentially violates the federal Emergency Medical Treatment and Active Labor Act (“EMTALA”), which requires hospitals to screen and stabilize all who present themselves to emergency departments for care. Hospitals must understand the contours and nuances of their responsibilities under EMTALA during disasters as well as ways in which they can protect themselves from liability for potential, but unavoidable, violations.

To help answer these questions, the Virginia Hospital and Healthcare Association engaged Troutman Sanders LLP to analyze the current state of EMTALA law with respect to disasters and draft this white paper for all Virginia hospitals. The results of this analysis are mixed. The good news is that, during an emergency or disaster, a hospital will be relieved of its EMTALA obligations in limited circumstances. The bad news is that, because these protections are so limited, hospitals must plan as if they will be responsible for fulfilling all EMTALA obligations even in the midst of a disaster.

II. Overview of EMTALA

In 1986, Congress enacted the Emergency Medical Treatment and Active Labor Act (“EMTALA”) to combat the perceived problem among hospital emergency departments of “patient dumping” – the transferring of under or uninsured patients prior to treatment.² Since then, CMS has issued both regulations in the Code of Federal Regulations³ and Interpretive Guidelines in the CMS State Operations Manual⁴ to help implement and outline hospitals’ responsibilities under the statute.

**Sources of
EMTALA
authority:**

- ❑ **Statute**
- ❑ **Regulation**
- ❑ **Interpretive Guidelines**

EMTALA mandates that a Medicare-participating hospital with a dedicated emergency department (“ED”) medically screen anyone who comes to the emergency department seeking treatment for a medical condition so as to determine whether an “emergency medical condition” (“EMC”) exists.⁵ The term “emergency medical condition” is defined to mean a medical condition that without immediate medical attention could result in “(i) placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy; (ii) serious impairment to bodily functions; or (iii) serious dysfunction of any bodily organ or part.”⁶

If, after conducting a Medical Screening Exam (“MSE”), it is determined that no emergency medical condition exists, the hospital’s EMTALA obligation ends and the individual

EMTALA requires hospitals to provide MSEs and stabilization care to all comers.

may be discharged, admitted to the hospital or transferred to another facility.⁷ If, however, the MSE shows that the patient has an emergency medical condition, the hospital is obligated under EMTALA to stabilize and/or transfer the individual to another hospital, depending on the specific circumstances.

Under EMTALA, an individual will be deemed “stabilized” if the physician attending to the patient has determined, within reasonable clinical confidence, that the emergency medical condition has been resolved, even though the underlying medical condition may persist.⁸ In general, the transfer of a non-stabilized patient may only be effected by a hospital (i) if the medical benefits of the transfer outweigh the risks or (ii) if the patient requests the transfer.⁹

Enforcement of EMTALA is a complaint driven process.¹⁰ Alleged violations of EMTALA are reported to the Centers for Medicare and Medicaid Services (“CMS”), usually by either a patient who was subjected to the alleged violation or hospitals that believe another hospital has violated its obligations.¹¹ CMS will initiate an investigation of the alleged violation, which will be conducted by the state Medicare survey agency. Among other things, the investigation should include an in-depth analysis of the hospital’s policies and processes governing triage, a record review for the specific complaint and interviews with facility staff involved in the alleged violation.¹² If CMS determines that an EMTALA violation has occurred, it may impose civil monetary penalties of up to \$50,000 for each violation.¹³

In addition to CMS’s investigative action, a person who suffers personal harm as a direct result of a hospital’s EMTALA violation may bring a civil action for damages and/or equitable relief against the hospital.¹⁴ If the plaintiff prevails in his suit, he is entitled to “obtain those damages available for personal injury under the law of the State in which the hospital is located.”¹⁵ In Virginia, the Fourth Circuit Court of Appeals has ruled that this provision makes Virginia’s malpractice cap applicable to recovery in EMLATA actions.¹⁶ This means that plaintiff’s in EMTALA actions are able to recover up to the amount authorized by Virginia’s malpractice cap.¹⁷

***Currently, the
medical malpractice
cap in Virginia is
\$1,850,000.***

III. EMTALA and Disasters

When EMTALA was enacted in 1986, emergency preparedness and response in relation to large scale disasters and potential pandemics was not on the forefront of the government's agenda. As a result, the original EMTALA legislation, which was meant to ensure that everyone who presented to an ED for treatment of an emergency medical condition received such treatment, did not have any exceptions for large scale disasters in which EDs would not be able to meet their obligations. In the wake of September 11th and the subsequent Anthrax attacks, CMS and Congress recognized the inadequacies of the law with respect to such events and sought to rectify this. Beginning with a letter from CMS to Regional Administrators and State Survey Agencies in November 2001, CMS and Congress have taken various actions to clarify the application of EMTALA in a large scale disaster or pandemic. These actions have resulted in a regulatory exception to EMTALA and a statute that gives the Secretary of HHS the ability to waive EMTALA requirements during specified disasters and emergencies.

a. Regulatory Exception for Otherwise Inappropriate Transfers During a National Emergency

The EMTALA regulations prohibit a hospital from transferring a patient who has an emergency medical condition prior to stabilization, unless the transfer is "appropriate."¹⁸ As described in the Overview, a transfer is generally appropriate where it has been requested by the patient or where a physician certifies that the medical risks are outweighed by the benefits of the transfer.¹⁹ During an emergency or disaster, it is foreseeable that hospitals will need to transfer patients to other facilities for a variety of reasons, but, because of the nature of the emergency or disaster, they will not be able to comply with the "appropriate" transfer regulations.

In 2003, CMS amended the EMTALA regulations to provide an exception for patient transfers during a national emergency. Under this exception, hospitals in “emergency areas” will not be subject to sanctions under EMTALA for inappropriate transfers during a national emergency.²⁰ While “national emergency” is not defined, “emergency area” is a defined term. It

The EMTALA TAG recently recommended expanding the exception to state, local and hospital-specific disasters.

means the geographical area in which there is a presidentially declared disaster or emergency under the Stafford Act²¹ or a public health emergency as declared by the Secretary under the Public Health Service Act.²²

Taken together, the use of both “emergency area” and national emergency means that the regulatory exception for transfers will only be available to those hospitals in areas of declared a disaster by the President or an area with a public health emergency by the Secretary. This exception will, therefore, not be available during hospital-specific, local or state declared emergencies and disasters for which there is no presidential declaration.²³

The Interpretive Guidelines unfortunately do not elaborate on the exception. These Guidelines only state that “CMS will issue guidelines as appropriate in the event of a national emergency and its impact upon the EMTALA regulations.”²⁴ The Guidelines do, however, elaborate on the applicability of the EMTALA requirements in general during a national emergency. Specifically, the Interpretive Guidelines state that while hospitals in the area of the national emergency will remain responsible for providing MSEs to all individuals who request examination or treatment, transfers or referrals of individuals in accordance with a “community response

Community disaster response plans should address hospital’s EMTALA obligations.

plan” will not result in sanctions under EMTALA.²⁵ There is no definition of “community response plans,” but the Guidelines suggest that a State or local EMS plan that designates specific entities with the responsibility of handling certain categories of patients during catastrophic events would qualify.²⁶ While the Interpretative Guidelines only specifically reference a State or local EMS plan, a fair interpretation of “community response plan” could include any emergency and disaster response plan at the state or local level.

Even with this broad interpretation, Virginia hospitals cannot take solace in this Guideline because Virginia’s state and local emergency preparedness and response plans were not written with this issue in mind. The plans, therefore, do not adequately address the EMTALA compliant transfer of certain categories of individuals to designated facilities during catastrophic events. The Virginia Department of Health is currently reviewing its pandemic influenza response plans and Troutman will suggest that the Department amend its plans appropriately.

b. Section 1135 Waiver

Congress has recognized that, in certain situations, enforcement of EMTALA requirements will need to be waived. In 2002, Congress enacted the Public Health Security and Bioterrorism Response Act, which added a Section 1135 to the Social Security Act. Upon a

The All Hazards and Pandemic Preparedness Act of 2006 expanded Section 1135 to include EMTALA waivers related to pandemics.

Presidential declaration of emergency or disaster pursuant to the Stafford Act²⁷ or a Secretarial declaration of public health emergency pursuant to the Public Health Service Act²⁸, Section 1135 authorizes the Secretary of HHS to “temporarily waive or modify

the application of” certain Medicare, Medicaid and SCHIP requirements to the extent necessary to exempt healthcare providers from sanctions when emergency circumstances have left them unable to comply with such requirements.²⁹ Included in the list of requirements for which sanctions can be waived are the EMTALA requirements.

Sanctions can be waived for both transfers and redirection. Specifically, the Secretary is empowered to waive sanctions for the “transfer of an individual who has not been stabilized in violation of [EMTALA] if the transfer arises out of the circumstances of the emergency.”³⁰ The Secretary may also waive sanctions for the direction or relocation of an individual to receive a MSE if the relocation is done pursuant to either an “appropriate State emergency preparedness plan” or, in the case of a declared public health emergency involving a pandemic infectious disease, a State pandemic preparedness plan.³¹

Waivers are generally limited to the 72-hour period beginning upon implementation of a hospital disaster protocol unless the Waiver arises out of a public health emergency involving a pandemic.³² If related to a pandemic, the Waiver terminates upon the first to occur of either the termination of the underlying declaration of a public health emergency or 60 days after being first published.³³ If the waiver terminates because of the latter, the Secretary may extend it for subsequent 60 day periods.³⁴

As alluded to above, the Secretary can only issue this Section 1135 Waiver for health care services rendered during an “emergency period” in an “emergency area.” The statute defines “emergency area” and “emergency period” as the geographical area and period (respectively) in which there is a presidentially declared disaster or emergency under the Stafford Act³⁵ or a public

***Section 1135 Waivers
are not available for
local and state
emergencies.***

health emergency as declared by the Secretary under the Public Health Service Act.³⁶ This means that Section 1135 waivers will not be available for local and state declared emergencies and disasters for which there is no presidential declaration.³⁷

In the wake of the Presidential declaration of emergency in Louisiana and surrounding states for Hurricane Katrina in August 2005,³⁸ the Secretary of HHS issued a Section 1135 Waiver related to various statutes and regulations, including EMTALA. Among other things, this waiver exempted hospitals in the affected areas from sanctions under EMTALA for the

The EMTALA Waiver issued post-Katrina was only effective for 72 hours.

“redirection of an individual to another location to receive a medical screening examination pursuant to a state emergency preparedness plan or transfer of an

individual who has not been stabilized if the redirection or transfer arises out of hurricane related emergency circumstances.” While it appears broad on its face, this waiver was only effective for 72 hours after hospitals implemented their hospital disaster protocols, as required by the Section 1135 statute.³⁹ After this 72 hour mark, hospitals had to comply with all EMTALA obligations or risk penalties for noncompliance.

During the time the waiver was in effect, hospitals were permitted to make otherwise prohibited transfers after conducting a medical screening exam so long as the transfer was necessitated by the disaster circumstances. Furthermore, hospitals were permitted to transfer patients *prior* to conducting a medical screening exam so long as such transfer was performed pursuant to a “state emergency preparedness plan.” If the state did not have an emergency preparedness plan which provided guidelines for such redirection, hospitals remained responsible for providing medical screening exams to all who came to its EDs.

When taken as a whole, the Section 1135 Waiver statute suggests that both the State emergency preparedness plan and the State pandemic preparedness plan should have language regarding the direction or relocation of an individual to receive a MSE in an alternative location. While Virginia does have robust emergency preparedness plans, these plans do not contemplate or provide guidelines for redirection of patients at a hospital prior to a medical screening exam. The Virginia Department of Health is currently reviewing its pandemic influenza response plans and Troutman will suggest that the Department amend its plans appropriately.

c. Hospital Responsibilities When Exceptions and Waivers Are Not Applicable

The exception and waiver discussed above will have limited applicability outside of Presidentially declared disasters. Even during such events, the protections from sanctions for EMTALA violations are sparse. Hospitals may remain obligated to provide a medical screening exam and stabilizing treatment for all who come to the ED during a disaster. While these are considerable responsibilities, hospitals may take solace in the fact that EMTALA only requires a hospital to provide these services “within the capabilities” of the facility. The remainder of this section will address this all important caveat as well as a hospital’s responsibility for performing a MSE, stabilization and transfer in a disaster.

A hospital is required to provide MSEs and stabilization care within its “capabilities”.

i. Capability

A disaster or emergency, whether local, state or national, will likely call into question a hospital's "capability" to provide medical screening exams, stabilization and transfers. "Capability" is a term of art in the EMTALA regulations. It is defined as "the ability of the hospital to accommodate the individual requesting examination or treatment of the transferred individual. [Capability] encompasses such things as numbers and availability of qualified staff, beds and equipment and the hospital's past practices of accommodating additional patients in excess of its occupancy limits."⁴⁰ The Interpretive Guidelines further elaborate on this issue stating that

Capabilities of a medical facility mean that there is physical space, equipment, supplies, and specialized services that the hospital provides (e.g., surgery, psychiatry, obstetrics, intensive care, pediatrics, trauma care).

Capabilities of the staff of a facility means the level of care that the personnel of the hospital can provide within the training and scope of their professional licenses. This includes coverage available through the hospitals [*sic*] on-call roster.⁴¹

The capacity to render care is not reflected simply by the number of persons occupying a specialized unit, the number of staff on duty, or the amount of equipment on the hospital's premises. *Capacity includes whatever a hospital customarily does to accommodate patients in excess of its occupancy limits...* If a hospital has customarily accommodated patients in excess of its occupancy limits by whatever mean [*sic*] (e.g., moving patients to other units, calling in additional staff, borrowing equipment from other facilities) it has, in fact, demonstrated the ability to provide services to patients in excess of its occupancy limits.⁴²

These Interpretive Guidelines have numerous implications for hospitals. Taken as a whole, the Guidelines suggest that a hospital has exceeded its capabilities only when it has

A hospital's "capability" includes its customary strategies for stretching resources.

exhausted its customary strategies to stretch its resources yet still cannot meet the needs of its ED patients. It is only at this point that hospitals do not

have the capabilities to fulfill their EMTALA obligations and can “close” their EDs by going on “diversionary status.”⁴³ “Diversionary status” signals to EMS providers that the hospital is unable to care for additional patients; therefore, any patients should be taken to other hospitals for medical care.

Most hospitals are familiar with, and have existing protocols that govern, implementation of diversionary status during “normal” times.⁴⁴ As in these normal diversions, during a disaster diversion, hospitals will continue to have EMTALA obligations with respect to patients who are in the ED when the hospital goes on diversion and those who come to the ED seeking treatment in spite of its closure. One CMS response to a “Frequently Asked Question” indicates that a hospital’s EMTALA obligation does not cease until it has evacuated all patients and staff from the ED thus leaving it with no capacity to render treatment.⁴⁵ This CMS interpretation will make it very difficult to argue that the hospital ED is “closed” even though care is still being provided in the ED for patients already in the hospital. With respect to these patients who remain in the ED or come to the ED, a hospital will be obligated to act within its capabilities to provide screening and, if necessary, stabilization. In a pandemic flu situation, this obligation may be particularly significant, given that many individuals, in particular the “worried well,” may come to the hospital of their own accord despite a declared closure of the ED.⁴⁶

In a disaster or emergency, hospitals should follow their current policies regarding diversion. In preparation for such an event, hospitals should consider modifying such policies to

(i) ensure that they will have sufficient documentation of the circumstances that led them to exceed their capabilities; (ii) specify the point at which the hospital is operating at capacity; (iii) provide the decision-

Hospitals should consider developing specific diversion policies related to a pandemic.

making authority for such a determination, (iv) outline notification mechanisms required by state or local law; and (v) establish transfer protocols consistent with EMTALA.

ii. Medical Screening Exams

Under current EMTALA law, hospitals will not be relieved of the obligation to perform a MSE even during disasters, unless a Section 1135 waiver is issued by the Secretary. The medical screening exam requirement is intimately tied to, and often confused with, triage. Triage refers to the ED's mechanism for prioritizing patient care. Because triage is usually based on the severity of the injury or illness (i.e. the most ill patients are seen first), many think that it is a basic medical screening exam. While in some respects it may be a screening, it is not a MSE

***Triage is
not equivalent to
an MSE.***

for purposes of EMTALA. In fact, the Interpretive Guidelines for EMTALA go so far as to state, “[t]riage is not equivalent to a medical screening examination. Triage merely determines the ‘order’ in which patients will be seen, not the presence or absence of an emergency medical condition.”⁴⁷

The Interpretive Guidelines further indicate that individuals coming to a hospital emergency department must be provided a MSE “beyond initial triaging.” Hospitals are understandably concerned about their ability to provide these exams in a timely fashion during disasters, if at all, for those with minor injuries or ailments. While a hospital cannot deny an individual a medical screening exam, it may be able to postpone it, provided that these individuals are *eventually* given a MSE.

EMTALA does not dictate a timeframe in which a MSE must be conducted. Instead, the regulations only prohibit a hospital from delaying a MSE to inquire about the individual's method of payment, insurance status, insurance pre-authorization or to complete a registration

process that “unduly discourage[s] individuals from remaining for further evaluation.”⁴⁸ The Interpretive Guidelines suggest that inquiries into screening delays are fact-specific and will be part of an investigation into the alleged violation:

If a delay in screening was due to an unusual internal crisis whereby it was simply not within the *capability* of the hospital to provide an appropriate screening examination at the time the individual came to the hospital (e.g., mass casualty occupying all the hospital’s resources for a time period), surveyors are to interview hospital staff members to elicit the facts surrounding the circumstances to help determine if there was a violation of EMTALA.⁴⁹

Consistent with these Interpretative Guidelines is a statement in the minutes of the November 2006 EMTALA Technical Advisory Group (“TAG”) meeting, which says that “CMS staff indicated they do look at emergency situations when investigating potential EMTALA violations, and the Office of the Inspector General takes such conditions under consideration when determining civil penalties.”⁵⁰ Implicit in the Guideline and comments from CMS staff is the recognition that the hospital will still be required to defend investigations. If the delays were the result of the “unusual internal crisis” and all patients were treated in a similar fashion (i.e. uninsured patients were not treated in a discriminatory fashion), surveyors will be hard-pressed to find an EMTALA violation. The burden is for the hospital to demonstrate the unusual circumstances, which underscores the importance of documentation of the unusual circumstances that compromised the hospital’s capabilities to provide timely MSEs for all patients.

While EMTALA requires a hospital to provide a MSE to all patients presenting to the ED requesting examination or treatment, it does not define the contours of such examination. The regulations only require that the MSE be performed in a manner that allows the clinician to determine whether an emergency medical condition exists,⁵¹ “nothing more, nothing less.”⁵² The scope of an appropriate MSE, therefore, will vary depending on the individual’s presenting symptoms and is typically left to the clinical judgment of the treating practitioner.⁵³ For example,

the EMTALA regulations clarify that individuals presenting in an ED for pharmaceutical services (i.e., prescription refills) need not be given a complete MSE, but rather, one that is appropriate for the request that they make.⁵⁴

This example was especially relevant following Hurricanes Katrina and Rita. Many evacuees from Louisiana, Mississippi, Alabama and Florida either lost or did not have copies of prescriptions when they evacuated affected areas. These evacuees presented to hospital EDs to obtain replacement prescriptions. CMS affirmed that such individuals need not be given a full EMTALA medical screening examination and suggested that hospitals develop specific protocols that include a streamlined screening examination for patients seeking prescription refills.⁵⁵ As this situation will likely occur after many types of disasters, hospitals should heed the advice of CMS and develop policies regarding MSEs for persons seeking prescription refills.

Although the content of the MSE is left to the discretion and clinical judgment of the clinician, the EMTALA regulations do require that MSEs be conducted by a “qualified medical person,” or “QMP.” A QMP may be either a physician or non-physician health care provider. Regardless, the QMPs must be designated by the hospital in a Board-approved document, typically its bylaws and/or its rules and regulations.⁵⁶ Importantly, the Interpretive Guidelines state that “[i]t is not acceptable for the hospital to allow informal [QMP] personnel appointments that could frequently change.”⁵⁷ Because traditional QMPs may not be available during a disaster or may be tasked with patient treatment instead of performance of a MSE, hospitals are well-advised to give forethought to adopting special disaster QMP designations (for appropriately qualified personnel) in a Board approved document.⁵⁸

***MSEs must be
conducted by QMPs
who are so
designated in a Board
approved document.***

iii. Stabilization and Transfer

After conducting a MSE and determining that an individual has an emergency medical condition, a hospital has an EMTALA obligation to provide stabilizing treatment or make an appropriate transfer of the patient to another facility. Under EMTALA, an individual will be deemed “stabilized” if the physician attending to the patient has determined, within reasonable clinical confidence, that the emergency medical condition has been resolved, even though the underlying medical condition may persist.⁵⁹ The “national emergency” exception does not relieve a hospital of this responsibility. Instead, the exception permits otherwise inappropriate transfers when a hospital does not have capacity or capability to render stabilization treatments.

This is congruent with the generally applicable rule that when a hospital has exhausted all of its capabilities in attempting to resolve an individual’s emergency medical condition, it must effect an appropriate transfer of the individual.⁶⁰ The Interpretive Guidelines support this by

Hospitals should transfer patients if they do not have the capability or capacity to stabilize the patient.

stating that “if the individual’s condition requires immediate medical stabilizing treatment and the *hospital is not able to attend to that individual because the emergency department is operating beyond its capacity*, then the hospital should transfer the individual to a hospital that has

the capability and capacity to treat the individual’s EMC.”⁶¹ Additionally, “a sending hospital’s appropriate transfer of an individual in accordance with community wide protocols in instances where it cannot provide stabilizing treatment would be deemed to indicate compliance with [EMTALA].”⁶²

While the exception and Interpretive Guidelines do relieve hospitals of their obligation to stabilize when they do not have the capabilities to do so, they solidify the hospital’s obligation to

effect a transfer to a hospital with such capabilities and capacity. Hospitals should be cautioned that if capacity levels in the ED have been reached and an individual with an EMC leaves the ED because the hospital is unable to timely attend to the condition, such a situation may present EMTALA liability. Specifically,

If a screening examination reveals an EMC and the individual is told to wait for treatment, but the individual leaves the hospital, the hospital did not “dump” the individual *unless...* the individual’s condition was an emergency, *but the hospital was operating beyond its capacity and did not attempt to transfer the individual to another facility.*⁶³

This Guideline emphasizes the importance of instituting policies and procedures that will control the hospital’s transfer of patients when it is not able to provide stabilization care because it is not within the facility’s capabilities. Again, hospitals should already have these policies and procedures in place, but they may need to be modified to reflect potential disaster circumstances.

One important caveat to this discussion of transfer, however, is the recognition that in a disaster or emergency situation, most, if not all, regional hospitals will likely be operating in excess of their capabilities. When that is the case, it is not clear to which facilities patients should be transferred. The situation may be further complicated by numerous factors including the unavailability of appropriate transport vehicles, the inability to traverse major roadways, or the inability to communicate with other facilities to inquire about capacity as a result of busy circuits or downed telephone

Transfers during disasters will be complicated by the very nature of the disaster.

lines.⁶⁴ In these circumstances, EMTALA provides little, if any, guidance. Hospitals should be advised to treat all patients in similar situations in the same way and do the best that they can. If circumstances become this burdensome and extreme, it is unlikely that CMS will find any violations of EMTALA for failure to stabilize or transport so long as hospitals act reasonably.

IV. Recommended Courses of Action to Ensure Compliance with EMTALA during Disasters and Emergencies

Because EMTALA was not drafted with an eye toward disaster and emergency circumstances, it in many respects fails to provide adequate relief for hospitals operating in the midst of such events. Despite limited administrative relief, hospitals will still be required to comply with their EMTALA obligations regarding MSEs, stabilizations and transfers during disasters. The ultimate solution to this problem lies with Congress through amendment to the law. Hospitals across the country may consider forming a coalition of healthcare providers to pursue amendment of EMTALA to incorporate greater exceptions for disaster circumstances.

Forming such a coalition is a formidable, yet worthwhile, project that could ultimately result in much needed relief for hospitals. Until the coalition completes its mission, however, hospitals should take steps to identify the ways in which it will meet its EMTALA obligations during disasters. Those steps include, but are not limited to, the following:

- The Virginia Department of Health is currently reviewing its pandemic influenza response plans and Troutman will suggest that the Department amend its plan appropriately;
- Consider modifying existing EMTALA diversion policies to (i) ensure that the hospital will have sufficient documentation of the circumstances that led it to exceed its capabilities; (ii) specify the point at which the hospital is operating at capacity; (iii) provide the decision-making authority for such a determination, (iv) outline notification mechanism required by state or local law; and (v) establish transfer protocols consistent with EMTALA;

- Develop policies regarding the scope and protocol for providing MSEs to persons seeking prescription refills;
- Adopting special disaster QMP designations (for appropriately qualified personnel) in a Board approved document; and
- Institute policies and procedures that will control the hospital's transfer of patients when it is not able to provide stabilization care because it is not within the facility's capabilities.

To the extent that hospitals appropriately plan for EMTALA compliance during an emergency or disaster, they will be in a better position to defend EMTALA claims that arise from the disaster.

Notes

¹ News about EMTALA at emtala.com (last visited August 8, 2006)

² 42 U.S.C. § 1395dd.

³ See generally 42 C.F.R. § 489.

⁴ See SOM, Appendix V-Interpretive Guidelines-Responsibilities Medicare Participating Hospitals in Emergency Cases, Part I, Interpretive Guidelines (Rev. 1, 05-21-04) (“Interpretive Guidelines”).

⁵ 42 U.S.C. § 1395dd. EMTALA does not apply to hospital inpatients or to individuals arriving at off-campus facilities that are not considered “dedicated emergency departments” under the law. See 42 C.F.R. § 489.24(d)(2)(ii); 68 Fed. Reg. 53,240 (Sept. 9, 2003).

⁶ 42 U.S.C. § 1395dd(e)(1).

⁷ Interpretive Guidelines Tag A406. See also *Slabik v. Sorrentino*, 891 F.Supp. 235 (E.D. Pa. 1995).

⁸ Interpretive Guidelines Tag A407.

⁹ *But see infra* Section I (discussion of patient transfer pursuant to community-wide disaster response plan).

¹⁰ See Interpretive Guidelines.

¹¹ See GAO-01-747, EMTALA Implementation and Enforcement Issues, U.S. General Accounting Office, June 2001.

¹² *Id.*

¹³ 42 U.S.C. § 1395dd(d)(1)(A). Physicians responsible for an EMTALA violation are likewise subject to civil monetary penalties up to \$50,000 and/or exclusion from the Medicare program (*see generally* 42 U.S.C. § 1395dd(d)(1)(B)). www.oig.hhs.gov/fraud/enforcement/administrative/cmp/cmphitemspd.html for a list of EMTALA related fines since 2002.

¹⁴ 42 U.S.C. § 1395dd(d)(2)(A). The statute of limitations for bringing a personal injury claim under EMTALA is two years (42 U.S.C. § 1395dd(d)(2)(C)).

¹⁵ *Id.*

¹⁶ See Va. Code § 8.01-581.15. See also *Power v. Arlington Hospital Assc.*, 42 F.3d 851(4th Cir. VA 1994)(holding that recovery for an EMTALA claim that fits within the broad rubric of malpractice actions is limited by Virginia’s malpractice cap).

¹⁷ Virginia imposes a cap on damages in medical malpractice cases. For claims arising out of acts or omissions on or after August 1, 1999, and before July 1, 2000, the cap is \$1.5 million. The cap limit of \$1.5 million increased on July 1, 2000, and increased each July 1 thereafter by \$50,000 per year. The two final increases on July 1, 2007 and July 1, 2008 will each increase the cap by \$75,000. Each annual increase applies to the act or acts of malpractice occurring on or after the effective date of the increase. Va. Code Ann. § 8.01-581.15.

¹⁸ 42 CFR § 489.24.

¹⁹ 42 CFR § 489.24(e).

²⁰ 42 CFR § 489.24(a)(2)

²¹ The Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121-5206 (the “Stafford Act”), was created to “provide an orderly and continuing means of assistance by the Federal Government to State and local government in carrying out their responsibilities to alleviate the suffering and damage which result from disasters.”(42 U.S.C. § 5121(b)) To accomplish this lofty goal, the Stafford Act establishes a process for requesting and obtaining a Presidential disaster declaration, defines the type and scope of assistance available from the Federal government, and describes the conditions for obtaining that assistance. The Stafford Act requires that “all requests for a declaration by the President that a major disaster exists shall be made by the Governor of the affected State.”(42 U.S.C. § 5170) The Governor must make his request through the regional Federal Emergency Management Agency (“FEMA”) office and take appropriate action to execute the state’s emergency plan. (See *A Guide to the Disaster Declaration Process and Federal Disaster Assistance*, Federal Emergency Management

Agency, available at http://www.fema.gov/pdf/rebuild/recover/dec_proc.pdf (last visited December 5, 2006). The Governor's request must include information on the nature and amount of state and local resources that have been or will be committed to alleviating the disaster, an estimate on the amount and severity of damage caused by the disaster, and an estimate of the amount of federal assistance that will be needed. Based on the Governor's request, the President may declare that a major disaster or emergency exists or deny the request.(Id.)

²² Section 319(a) of the Public Health Service (PHS) Act, authorizes the Secretary of the Department of Health and Human Services (HHS) to declare a public health emergency and "take such action as may be appropriate to respond" to that emergency consistent with existing authorities. (42 U.S.C. § 247d.) The Secretary may declare a public health emergency when, after consultation with public health officials, he finds that "a disease or disorder presents a public health emergency or a public health emergency, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists."(42 U.S.C. § 247d(a))

²³ The EMTALA Technical Advisory Group ("TAG") recently recommended this exception be expanded to provide protections during declared state, county and city emergencies as well as hospital-specific emergencies as determined by CMS/OIG on a case-by-case basis. This would be a significant expansion of the existing regulation. See *Report Number Five to the Secretary of U.S. Department of Health and Human Services From the Emergency Medical Treatment and Labor Act Technical Advisory Group*, November 2-3, 2006 (issued February 6, 2007) (available at https://www.cms/hhs.gov/FACA/07_emtalatag.asp).

²⁴ Interpretive Guidelines § 489.24(a)(2).

²⁵ TAG A406 Interpretative Guidelines § 489.24(a).

²⁶ Id.

²⁷ See note 21.

²⁸ See note 22.

²⁹ 42 U.S.C. § 1320b-5(a)(2).

³⁰ 42 U.S.C. § 1320b-5(b)(3)(A).

³¹ 42 U.S.C. § 1320b-5(b)(3)(B).

³² 42 U.S.C. § 1320b-5(b). The EMTALA TAG is recommending that the 72-hour limitation be extended to allow the waiver to remain in effect until the hospital is no longer in an emergency situation or the government-declared emergency has been terminated. See note 23.

³³ 42 U.S.C. § 1320b-5(e).

³⁴ Id.

³⁵ Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121-5206.

³⁶ Id. and the Public Health Service Act P.L. 109-374, 42 U.S.C. § 201 et seq.

³⁷ The EMTALA TAG recently recommended that Section 1135 Waivers be expanded to provide protections to include declared state, county and city emergencies as well as hospital-specific emergencies as determined by CMS/OIG on a case-by-case basis. See note 23.

³⁸ See Statement on Federal Emergency Assistance for Louisiana issued The White House, August 27, 2005, available at <http://www.whitehouse.gov/news/releases/2005/08/20050827-1.html> (last visited December 5, 2006).

³⁹ 42 U.S.C. 1320b-5(b)(3).

⁴⁰ 42 CFR § 489.24(b). Note: the definition is quoted above is the definition of "capacity." "Capacity" is not used in the statute, but the term "capability" is. We assume that these two words are interchangeable and reflect confusion in the legislative drafting process.

⁴¹ Interpretive Guidelines Tag A407. *See also* Interpretive Guidelines Tag A406: “Hospital resources and staff available to inpatients at the hospital for emergency services must likewise be available to individuals coming to the hospital for examination and treatment of an EMC because these resources are within the capability of the hospital.”

⁴² Interpretive Guidelines Tag A407.

⁴³ *See* <http://questions.cms.hhs.gov>, Question #6010 (last visited May 12, 2006). Question #6010 asks, “[i]f a Hospital remains open during a disaster like Hurricane Rita and is operating at or in excess of its normal operating capacity and cannot get sufficient staff, may the hospital shut down its emergency department (ED) without violating EMTALA?” The answer is as follows:

Under these circumstances, EMTALA would not prohibit the hospital from closing its ED to new patients (in effect, going on diversion)... The hospital would continue to have an EMTALA obligation to individuals undergoing examination or treatment in its ED at the time it stops accepting new emergency patients. In addition, if any individual comes to such a hospital and requests examination or treatment for an [EMC], the hospital would be obligated by EMTALA to act *within its capabilities* to provide screening and, if necessary, stabilization.

⁴⁴ These policies, procedures and protocols should provide, *inter alia*, that a hospital should comply “to the extent circumstances permit” with any state or local notification requirements and follow its own established procedure for notification of diversionary status. CMS has indicated that during an emergency, a hospital will not be in violation of EMTALA if it transfers a patient without obtaining prior acceptance from the receiving hospital because telephone circuits are busy. In such a situation, a determination will be made as to whether the hospital acted reasonably and in the patient’s best interest in transferring the patient without a proceeding agreement to accept. *See* <http://questions.cms.hhs.gov>, Question #6009 (last visited May 12, 2006).

⁴⁵ *See* <http://questions.cms.hhs.gov>, Question #6008 (last visited May 12, 2006). Question #6008 asks whether a hospital that is evacuating in response to a mandatory or voluntary evacuation order may close its ED when it begins its evacuation. Again, CMS states that the hospital may close its ED to new patients (i.e., go on diversionary status), but must continue to attend (as appropriate) to its current ED patients. CMS further explains that, “[i]n most cases, this would mean that individuals would receive only triage followed by the minimum level of care needed to protect their health and safety while they and other patients are being evacuated to a site where screening and stabilization can be provided. Once the ED patients and staff have been evacuated and the ED has no capacity to render treatment, the hospital would no longer be obligated under EMTALA.”

⁴⁶ It is important to note that a hospital’s obligations under EMTALA apply not only to individuals who “come to the emergency department,” but may also apply to individuals who are elsewhere on hospital property. (*See generally* 42 CFR § 489.24(a) and Interpretive Guidelines Tag A406 for discussion of “hospital property,” which is applicable for public emergency and non-public emergency situations alike.) For the worried well in a pandemic flu outbreak, it is plausible, and perhaps more likely, that such individuals would present on hospital property other than the ED, seeking treatment for an emergency medical condition. Hospitals should re-familiarize themselves with protocols for treating non-ED EMTALA patients.

⁴⁷ *See* Interpretive Guidelines TAG A406.

⁴⁸ 42 CFR § 489.24(d)(4)

⁴⁹ Interpretive Guidelines Tag A408 (emphasis added).

⁵⁰ *See infra* note 17.

⁵¹ 42 CFR § 489.24(a)(i)

⁵² *Collins v. DePaul Hosp.*, 963 F.2d 303, 306-07 (10th Cir. 1992); *see also Vickers v. Nash General Hosp., Inc.*, 78 F.3d 139 (4th Cir. 1996); *Power v. Arlington Hosp. Assoc.*, 42 F.3d 851, 856 (4th Cir. 1994).

⁵³ An appropriate MSE includes ancillary services routinely available to the ED that may be necessary to treat the individual. 42 C.F.R. § 489.24(a)(1)(i). Such ancillary services may include, for example, imaging services available at a separate, on-campus hospital building. Depending on the circumstances, ancillary services “routinely available to the ED” may not be accessible in a disaster or emergency. While there is no specific guidance on the

issue, it is unlikely that a hospital would be found to “violate” EMTALA in such a situation if it cannot offer ancillary services to its ED patients. Hospital emergency departments should, to the extent possible, attempt to stay updated on the capacity levels of other hospital service units during a disaster or emergency.

⁵⁴ 42 CFR § 489.24(c); *see* 68 Fed. Reg. 53,235 (Sept. 9, 2003). *See also* Interpretive Guidelines Tag A406, which notes that if an individual presents to an ED and requests services that are not for a medical condition, such as preventative care services (immunizations, allergy shots, flu shots) or the gathering of evidence for criminal law cases, the hospital is not obligated to provide an EMC.

⁵⁵ *See* <http://questions.cms.hhs.gov>, Question #5695 (last visited May 12, 2006).

⁵⁶ 42 CFR § 489.24(a).

⁵⁷ Interpretive Guidelines Tag A406.

⁵⁸ The EMTALA TAG recommends that the EMTALA regulations and Interpretative Guidelines be amended to permit the use of person not normally deemed “QMPs” to provide MSEs and stabilization services during an emergency or disaster. Alternatively, the EMTALA TAG recommends that hospitals add additional categories of QMPs in their disaster plans. *See* note 23.

⁵⁹ Interpretive Guidelines Tag A407.

⁶⁰ 42 CFR § 489.24(e)

⁶¹ Interpretive Guidelines Tag A407 § 489.25(d)(1)(ii) (emphasis added)

⁶² Interpretive Guidelines Tag A407 § 489.24(d)(1)(i)

⁶³ Interpretive Guidelines Tag A406 (emphasis added).

⁶⁴ *See* <http://questions.cms.hhs.gov>, Question #6009 (last visited May 12, 2006). CMS indicated that during an emergency where all the circuits were busy such that a transferring hospital was unable to get acceptance before transfer, surveyors should “determine whether, given the absence of communication in the area, the hospital acted reasonably and in the patient’s best interest in transferring the patient without an agreement to accept the patient.”

APPENDIX E

REFERENCE LIST – ALTERED STANDARDS OF CARE LITERATURE

Altered Standards of Care Literature

- AHRQ's *Altered Standards of Care in Mass Casualty Events* (April 2005)
- HHS *Pandemic Influenza Plan* (November 2005)
- Institute of Medicine's *Modeling Community Containment for Pandemic Influenza: A Letter Report* (2006)
- Institute of Medicine's *Reusability of Facemasks During an Influenza Pandemic: Facing the Flu* (2006)
- WHO *Rapid Advice Guidelines on Pharmacological Management of Humans Infected with Avian Influenza A (H5N1) Virus* (2006)
- WHO's *Global Consultation on Addressing Ethical Issues in Pandemic Influenza Planning* (October 2006)
- AHRQ's *Providing Mass Medical Care with Scarce Resources: A Community Planning Guide* (November 2006)
- Ontario Health Plan for Influenza Pandemic's *Development of a Triage Protocol for Critical Care During an Influenza Pandemic* (November 2006)
- CDC's *Interim Pre-pandemic Planning Guidance: Community Strategy for Pandemic Influenza Mitigation in the U.S. – Early, Targeted, Layered Use of Nonpharmaceutical Interventions* (February 2007)
- New York Department of Health's *Allocation of Ventilators in an Influenza Pandemic: Planning Document* (March 2007)
- North Carolina Institute of Medicine's *Stockpiling Solutions: NC's Ethical Guidelines for an Influenza Pandemic* (April 2007)
- CDC and DHHS' *In a Moment's Notice: Surge Capacity for Terrorist Bombings – Challenges and Proposed Solutions* (April 2007)
- WHO *Interim Protocol: Rapid Operations to Contain the Initial Emergence of Pandemic Influenza* (May 2007)
- California Department of Health Services' *Development of Standards and Guidelines for Healthcare Surge during Emergencies* (mid 2007)
- Security and Prosperity Partnership of North America's *North American Plan for Avian & Pandemic Influenza* (August 2007)
- GAO's *Influenza Pandemic: Opportunities Exist to Address Critical Infrastructure Protection Challenges That Require Federal and Private Sector Coordination* (October 2007)
- CDC's *Proposed Considerations for Antiviral Drug Stockpiling by Employers in Preparation for an Influenza Pandemic* (draft, October 2007)
- CDC's *Proposed Guidance on Antiviral Drug Use Strategies During an Influenza Pandemic* (draft, November 2007)
- OSHA's *Guidance on Preparing Workplaces for an Influenza Pandemic* (2007)
- OSHA's *Pandemic Influenza Preparedness and Response Guidance for Healthcare Workers and Healthcare Employers* (2007)
- ACLU's *Pandemic Preparedness: The Need for a Public Health – Not a Law Enforcement/National Security – Approach* (January 2008)
- CDC's *Influenza Pandemic Operation Plan* (January 2008)

- Task Force for Mass Critical Care Summit Report, published in *Chest* (May 2008)
- Harvard School of Public Health and Massachusetts Department of Public Health Altered Standards of Care Survey (current in process)

APPENDIX F

TROUTMAN SANDERS, LLP. *CRITICAL
RESOURCE SHORTAGES: A PLANNING
GUIDE.* JUNE 2008

**TROUTMAN
SANDERS**



Critical Resource Shortages: A Planning Guide

**Prepared by:
Steve Gravely, J.D., M.H.A.
Erin Whaley, J.D., M.A.
Troutman Sanders LLP**

**Prepared for:
Virginia Department of Health
Virginia Hospital and Healthcare Association
Altered Standards of Care Work Group**

JUNE 2008

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INTRODUCTION

Most experts, scholars and healthcare providers agree that during a pandemic the healthcare system's ability to continue to provide care will be compromised. The challenge for providers, especially hospitals, is to plan to continue providing care in the face of severe resource shortages combined with an influx of large numbers of very sick patients. To do this, hospitals must create both internal plans that dictate how the hospital will surge and allocate scarce resources, and external plans that build collaborative relationships with other healthcare providers and key community resources which complement and support the hospital's internal plans.

Healthcare providers are not accustomed to having to allocate inadequate personnel, equipment and supplies on the scale they will confront in a pandemic. The prospects of allocation on this scale, understandably, cause profound concern within the healthcare community because such decisions are inextricably tied to liability. These providers understand that they have a duty to render care in accordance with the applicable standard of care or face liability for malpractice. "Altered" standards of care, which by definition do not meet the traditional standard of care, implicate and exacerbate these concerns.

Providers in Virginia, both hospitals and physicians, expressed concerns about this very issue to VHHA. These concerns were so strong that, at the extreme, some providers were contemplating closing their doors during a pandemic instead of providing care under "altered" standards unless they had some degree of liability protection. VHHA recognized the gravity of the situation and, in coordination with VDH, engaged Troutman Sanders LLP to help it address this issue.

VDH, VHHA and Troutman Sanders (the "Core Team") recognized that there were substantial misconceptions and confusion among healthcare providers about their realistic liability exposure in relation to "altered" standards. The first step in developing a comprehensive strategy for addressing providers' concerns was for Troutman Sanders to evaluate the current law to determine if any of the liability concerns were legitimate. This evaluation consisted of: (i) an inventory of relevant Virginia laws including the Virginia Emergency Services and Disaster Law, the Virginia Good Samaritan Law, the Virginia State Government Volunteers Act, the statutory "standard of care" in Virginia, and Virginia's Model Jury Instructions for medical malpractice; and (ii) an analysis of applicable laws in relation to a potential "altered" standard of care case, licensure and scope of practice restrictions. Troutman developed a White Paper summarizing its legal analysis that is available as a resource for all Virginia healthcare providers. This legal analysis confirmed that there was indeed a gap in liability protection that left healthcare providers vulnerable to potential claims of malpractice for care provided pursuant to "altered" standards during a disaster.

Beginning in 2006, the Core Team convened a multi-disciplinary, state-wide work group to evaluate options to address the liability associated with "altered" standards of care (the "Altered Standards Work Group"). The Core Team selected members for the Altered Standards Work Group to assure that diverse perspectives were present without creating a group that was too large to be effective. The Altered Standards Work Group was composed of individuals from across the state who represent various healthcare institutions, clinician groups, public health,

emergency planning bodies and a state legislator. The Altered Standards Work Group sessions were facilitated by Troutman because of their extensive experience in representing both health providers and public health interests, which enabled them to understand the perspective of each stake holder.

The Troutman Sanders White Paper helped dispel common misconceptions about liability during disasters and assured that all members of the Altered Standards Work Group had the same basic background information. This helped the Altered Standards Work Group to realize that liability in an “altered” standard of care sense was a function of two separate but related components: the existing “black letter” law and how that law is likely to be applied to a disaster situation involving the actual delivery of care. The Altered Standards Work Group decided to pursue a two-tiered approach to addressing the issue: suggesting legislative solutions and drafting practical guidance for hospitals to help them determine how to actually deliver care in the face of scarce resources.

When the Altered Standards Work Group first convened, legislative solutions were neither immediate nor guaranteed. As a result, the Altered Standards Work Group pursued a strategy which would allow them to create a tool to help hospitals think and plan for providing care with limited resources. While a few others across the country had devised specific “altered” standard of care algorithms for the allocation of specific resources, like ventilators, the Altered Standards Work Group could find no comprehensive planning guide on which to base its work. In the absence if any definitive tools, the Altered Standards Work Group undertook an ambitious project of creating such a guide from whole cloth (the “Critical Resource Shortage Planning Guide” or “Planning Guide”).

The Altered Standards Work Group had to come to a consensus on key assumptions regarding the provision of healthcare with scarce resources which will lead to an “altered” standard of care. The three most basic assumptions are as follows:

1. When talking about “altered” standards of care, we are really talking about allocation of critical resources in times of shortage. Critical resources are those that are required to sustain human life, prevent permanent disability, or stabilize a person experiencing a medical emergency. These resources will include staff, space and “stuff” such as equipment, medications and supplies.
2. While it is commonly recognized within the healthcare industry that “altered” standards of care will have to be employed during a disaster, there is no consistency about the exact nature of those standards. Each disaster situation is unique, as is each healthcare community. This makes it difficult to formulate universal, rigid “altered” standards of care in advance. Instead, it will be most beneficial to offer a *process* that providers can use to identify the content of such standards. That process can then be utilized to develop “altered” standards algorithms as the need arises. This is especially true with a pandemic in which high absenteeism rates will make health care staff in very short supply. In addition, the process can be used to create mechanisms at a healthcare facility to implement an “altered” standard of care if one is promulgated by the state or federal government (e.g. ventilator algorithms).
3. Hospitals will allocate scarce resources in a way that does the greatest good for the greatest number, as determined by the provider.

Recognizing the enormously complex ramifications of these assumptions, the Altered Standards Work Group focused its efforts on creating a tool that provides a systematic approach to addressing the complex issues surrounding the allocation and deployment of scarce resources during large scale events, like a pandemic. The result of the effort is the Planning Guide which provides a specific, detailed decision matrix that healthcare providers across the nation can use to anticipate and respond to shortages of critical resources during an event. The Planning Guide walks a provider step-by-step through the key stakeholders that should be involved in “altered” standards planning, the questions that need to be asked, the decisions that need to be made and the interdependencies that must be taken into account. Even with all of this specificity, the Guide is flexible enough to be used by a 900 bed academic medical center and a 15 bed critical access hospital.

The Core Team and the Work Group hope that this Planning Guide will be a useful tool for hospitals to use in their pandemic preparedness efforts. Any questions about the Guide can be directed to Steve Gravely at (804) 697-1308 or steve.gravely@troutmansanders.com or Erin Whaley at (804) 697-1389 or erin.whaley@troutmansanders.com.

DEFINITIONS

Critical Resource: A resource that is necessary to provide care to sustain human life, prevent permanent injury/disability or stabilize a patient experiencing a medical emergency. Critical Resources can include people, places and things.

Critical Resource Shortage: A circumstance in which a Critical Resource is depleted, and all alternate methods of obtaining the Critical Resource have been exhausted, such that remaining resources will not allow a hospital to treat patients in accordance with the traditional standard of care.

Critical Resource Shortage Response Plan: That treatment protocol created in response to a Critical Resource Shortage caused by an Emergency or Disaster, as defined in Title 44 of the Code of Virginia (see Appendix 1), pursuant to which scarce Critical Resources are allocated to do the most good for the greatest number of patients.

Emergency or Disaster: Those community and statewide Emergencies and Disasters that are encompassed in the definitions in Title 44 of the Code of Virginia.¹ See Appendix 1 for a list of current definitions.

¹ This limitation is necessary as the legislative initiatives are tied to Title 44 definitions. Note: this does not mean that the Disaster needs to be a declared emergency. It only means that it must fall within the definitions of Emergencies and Disasters in Title 44.

PLANNING GUIDANCE

Pre-Event/Preparedness Phase: There are certain resources for which it is foreseeable that during an Emergency or Disaster there will be a Critical Resource Shortage. For these items, a facility should determine how it will respond to the Critical Resource Shortage before the event occurs.

Planning Committee:

1. Identify an existing committee(s) or establish a new committee that will be responsible for conducting a Critical Resource Vulnerability Analysis and establishing baseline principles that will be used when determining how to respond to a Critical Resource Shortage.
 - 1.1. Obtain representation from appropriate nursing specialties (e.g. critical care, emergency department, floor and operating room), medical staff leadership, physicians from appropriate specialties (e.g. intensivists, surgeons, internal medicine, pediatrics, emergency medicine, trauma, hospitalists, primary care, palliative care), and representatives from therapy services, administration, laboratory, pharmacy, information systems (whoever is involved in results reporting, e.g. lab, x-ray), ethics, legal, and Incident Command (logistics, planning and operations – clinical).
 - 1.2. If hospital chooses to use multiple committees to perform these functions, ensure that there is one person who is responsible for management and oversight of the various committee responsibilities and the process in general.

Critical Resource Vulnerability Analysis:

2. Conduct a Critical Resource Vulnerability Analysis to determine which Critical Resources may become limited in the event of an Emergency or Disaster.
 - 2.1.1. The group tasked with conducting this analysis should brainstorm and create a list of all those resources necessary to sustain human life, prevent permanent injury/disability or stabilize a patient experiencing a medical emergency.
 - 2.1.2. Resources should be categorized as equipment/supplies, physical space or personnel.
 - 2.1.3. With respect to personnel, the group should identify those skill sets that will be needed to respond to the Emergencies and Disasters identified in the facility's most recent hazard vulnerability analysis. Once skill sets are identified, they should be classified as a "Critical Resource" if they are necessary to sustain human life, prevent permanent injury/disability or stabilize a patient experiencing a medical emergency, or if few people within the facility have this skill set and cross training or just-in-time training is not practical or realistic because of the specialization of the skill.
 - 2.1.4. See Appendix 2 for a sample list of Critical Resources.

- 2.1.5. The Critical Resource Vulnerability Analysis could be facility specific or system specific based upon the resources of the facility/system and the most likely threats.
- 2.2. Prioritize those resources identified in the Critical Resource Vulnerability Analysis by determining which of the resources are most likely to be depleted causing a Critical Resource Shortage.
 - 2.2.1. When making this determination consider which resources, when depleted, will have the greatest impact on sustaining patient's lives and which resources are most likely to be critically important and/or depleted in light of the hospital's most current hazard vulnerability analysis.
 - 2.2.2. Example: A hospital's top Disaster may be a chemical explosion at a nearby plant. This will cause a large influx of burn patients. Burn care kits will be in high demand and likely depleted. Burn care kits are, therefore, on the top of the hospital's Critical Resource list.
- 2.3. Identify mechanisms for mitigating depletion of the Critical Resource for the resources as identified in and prioritized by the Critical Resource Vulnerability Analysis. Examples of mitigation mechanisms include:
 - 2.3.1. Stockpiling;
 - 2.3.2. MOAs/MOUs for resource sharing; and,
 - 2.3.3. Modification and/or substitution with other resources (e.g. substituting ambu-bags for ventilators).
- 2.4. Revisit the Critical Resource Vulnerability Analysis at least once every two years or after an Emergency or Disaster.

Baseline Ethical Principles:

3. Establish baseline ethical principles to guide the response to Critical Resource Shortages and the development of specific Critical Resource Shortage Response Plans.
 - 3.1. Consider the following general principles when answering the questions in this Section 3:
 - 3.1.1. Respect for patient and health care provider autonomy;
 - 3.1.2. Beneficence (who will benefit from the decision?);
 - 3.1.3. Non-maleficence (minimize the risk of harm);
 - 3.1.4. Distributive justice (fundamental fairness);
 - 3.1.5. Transparency of process;
 - 3.1.6. Stewardship of resources; and,
 - 3.1.7. Accountability.
 - 3.2. What does it mean to provide the greatest good for the greatest number?

- 3.3. During a Critical Resource Shortage, will providers be allowed to withdraw or stop providing the Critical Resource to one patient to give to another patient for whom the Critical Resource is more appropriate or beneficial or will providers have to adhere to a “first come, first served” policy?
- 3.4. What resources should be given to those patients who are not given the Critical Resource?
- 3.4.1. Should these patients be given alternative resources, if available?
 - 3.4.2. Should these patients and their families be given palliative care? If so, refer to Section 3.5.
 - 3.4.3. Should these patients remain in the facility, be discharged or transferred to another facility (e.g. alternative care center)?
 - 3.4.4. Who will make these decisions?
- 3.5. Palliative Care
- 3.5.1. What is the goal of palliative care during a Critical Resource Shortage?
 - 3.5.1.1. To relieve pain?
 - 3.5.1.2. To manage symptoms without use of the Critical Resource in question?
 - 3.5.1.3. To ensure that patients are not abandoned even though they are not receiving the Critical Resource?
 - 3.5.1.4. Other goals?
 - 3.5.1.5. Remember that there will likely be individuals receiving palliative care during a Critical Resource Shortage who would not have received palliative care during normal times when the Critical Resource was readily available.
 - 3.5.2. How will your facility define palliative care during a Critical Resource Shortage? Consider the following definitions:
 - 3.5.2.1. World Health Organization: “An approach which improves the quality of life of patients and their families facing life-threatening illness, through the prevention, assessment, and treatment of pain and other physical, psychosocial, and spiritual problems.”
 - 3.5.2.2. Joint Commission: “Palliative care is an approach designed to improve the quality of life of patients and their families by relieving the pain, symptoms and stress of serious illnesses such as cancer or AIDS.”
 - 3.5.2.3. National Consensus Project for Quality Palliative Care: “Palliative care focuses on the relief of suffering and distress for people facing serious, life-threatening illness to help them and their families to have the best possible quality of life, regardless of the stage of the disease or the need for other therapies. Palliative care is both a philosophy of care and an organized, highly structured system for delivering care. Palliative care expands traditional disease-model medical treatments to include the goals of enhancing quality of life for patient and family, optimizing function, helping with decision making, and providing opportunities for personal growth. As

such, it can be delivered concurrently with life-prolonging care or as the main focus of care.”

3.5.3. Review your facility’s existing protocols, policies and procedures for palliative care during normal times.

3.5.3.1. How should these be modified for use during a Critical Resource Shortage? Refer to Sections 3.5.1 and 3.5.2 when modifying these policies.

3.5.4. Who will provide palliative care?

3.5.4.1. What training is needed to prepare these individuals?

3.5.4.2. What emotional and psychological support will be provided for these individuals?

3.5.5. Are there palliative care support organizations in your area that can provide assistance?

3.6. Are there any factors or patient characteristics that should not be factored into allocation decisions and specific Critical Resource Shortage Response Plans? Consider the following as inappropriate characteristics on which to base allocation decisions: ability to pay; social worth; patient contribution to the disease; past use of resources; race or ethnicity; religion; and gender. (See California Department of Health Services for examples of inappropriate exclusion criteria <http://bepreparedcalifornia.ca.gov/EPO/CDPHPrograms/PublicHealthPrograms/EmergencyPreparednessOffice/EPOProgramsServices/Surge/SurgeStandardsGuidelines/>).

3.7. Decisions about issues presented in Section 3 should be recorded and communicated to each group charged with developing Critical Resource Shortage Response Plans for specific Critical Resources identified in the Critical Resource Vulnerability Analysis.

Operational Issues:

4. Address the following operational issues to guide the development of specific Critical Resource Shortage Response Plans.

4.1. Consider the following general operational issues.

4.1.1. Who is the most appropriate person within the organization to identify a Critical Resource Shortage? Is this a CEO level decision or a clinical operations decision?

4.1.2. To whom within your incident command structure should this finding be reported?

4.1.3. Who within your incident command structure will declare that a Critical Resource Shortage exists?

4.1.4. Who within your incident command structure will authorize the implementation of Critical Resource Shortage Response Plans?

4.1.5. Who within your incident command structure is responsible for obtaining and reviewing the state or local emergency declaration, if one is made?

- 4.1.6. Once implementation of a Critical Resource Shortage Response Plan is authorized, who within your organization will be designated to make the allocation decisions based on the Critical Resource Shortage Response Plan? Will this be one person, a committee, or will individual treating physicians be charged with this duty?
 - 4.1.6.1. If your facility chooses to designate a person(s), how will they be selected? Will the selection be dependent upon the resource that is scarce or will the selection remain consistent for all resources? Will the committee be the same as the one created in Section 1? Will it be a subset of the committee in Section 1, or will it be composed of different individuals?
 - 4.1.6.2. What powers will the designated person(s) have?
 - 4.1.6.3. How will the designated person(s) interact with Incident Command, specifically Medical Control and Resource Management?
 - 4.1.6.4. How will the designated person(s) interact and coordinate with Medical Control regarding non-compliant physicians? (See Section 4.1.12)
 - 4.1.6.5. Can the facility offer additional liability protection for these individuals in recognition of the difficult decisions they will have to make?
 - 4.1.6.6. Is the designated person(s) covered for decisions made in this role by the facility's insurance policy? If not, should the person(s) be added to the facility's insurance policy for this purpose?
- 4.1.7. Once a Critical Resource Shortage Response Plan is activated, how often will the Critical Resource Shortage situation be re-assessed during the event to determine if changes should be made to the response plan?
 - 4.1.7.1. Who within incident command will be responsible for monitoring the situation?
 - 4.1.7.2. To whom will they report significant changes in the situation?
 - 4.1.7.3. Who is responsible for altering the Critical Resource Shortage Response Plan to accommodate the new situation? Will the person(s) be dependent upon the resource that is scarce or will the person(s) remain consistent for all resources?
 - 4.1.7.4. How will these intra-event changes be communicated to staff for implementation?
 - 4.1.7.5. How will these intra-event changes be documented?
- 4.1.8. When should Critical Resource Shortage Response Plans be terminated?
- 4.1.9. Who within your incident command structure will authorize termination of Critical Resource Shortage Response Plans?
- 4.1.10. During Emergencies and Disasters, what type of documentation will practitioners be required to complete? This documentation can be referred to as "essential documentation."

- 4.1.11. What mechanisms will be used to keep facility personnel updated and informed about the implementation of, content of, modifications to, and termination of Critical Resources Shortages Response Plans? See Section 8.4 for information on inclusion of these mechanisms in your EOP.
- 4.1.12. What should happen when a physician chooses not to comply with a Critical Resource Shortage Response Plan?
 - 4.1.12.1. Review Medical Staff bylaws to determine current enforcement powers during an Emergency or Disaster.
 - 4.1.12.2. Identify Medical Control for the facility.
 - 4.1.12.3. Should Medical Control have the authority to take over patient care from individual physicians? If so, is this reflected in the Medical Staff bylaws and in the facility's EOP?
 - 4.1.12.4. How will the hospital address clinicians who refuse to operate outside their scope of practice when such is required by the Critical Resource Shortage Response Plan?
 - 4.1.12.5. Modify the hospital's EOP and Medical Staff Bylaws accordingly.
- 4.1.13. What mechanisms will be used to provide support and recovery services to employees, patients, and families during the intra-event/response and post-event/recovery phases?
 - 4.1.13.1. What services will be provided?
 - 4.1.13.2. Will the facility provide these services or will they contract with an outside organization (e.g. EAP) to provide them?
 - 4.1.13.3. Facility Human Resources professionals should be involved with developing these mechanisms.
- 4.2. Decisions about issues presented in Section 4 should be recorded and communicated to each group charged with developing Critical Resource Shortage Response Plans for specific Critical Resources identified in the Critical Resource Vulnerability Analysis.

Critical Resource Shortage Response Plan Development:

- 5. Develop Critical Resource Shortage Response Plans to address the resources identified in the Critical Resource Vulnerability Analysis according to the prioritization. For critical shortages of material resources, refer to Section 5.2. For a critical shortage of physical space, refer to Section 5.3. For a critical personnel shortage, refer to Section 5.4.
 - 5.1. For each Critical Resource identified in the Vulnerability Analysis, assemble a small group tasked with developing a Critical Resource Shortage Response Plan to address the shortage of the specific Critical Resource in question.
 - 5.1.1. Groups should be composed of at least one facilitator, IC (logistics, planning and/or operations – clinical), at least two physicians representing the relevant field/specialty, a nurse representing the relevant field/specialty, a palliative care

specialist (if available), any other type of clinician representing those whose practice will be impacted by the Critical Resource Shortage, an administrative representative, and a representative of the ethics committee.

- 5.1.2. Groups should be subcommittees of the committee(s) that conducted the Critical Resource Vulnerability Analysis.

Critical Shortage of Material Resources:

5.2. Using the ethical and operational principles developed in Sections 3 and 4 of this Planning Guide, respectively, each small group should address the following issues with respect to the specific critical *material resource* (e.g. equipment, medications) in question to create a Critical Resource Shortage Response Plan.

- 5.2.1. Does the hospital already have a plan in place to mitigate a shortage? If not, such a plan should be created. If so, the remainder of this planning process assumes that mitigation is no longer a feasible option.

- 5.2.1.1. This will require an evaluation of the facility's "surge" plan and its plans to share resources with other facilities in its region.

- 5.2.2. At what point will a Critical Resource Shortage exist? At what point will clinicians have to change their practice based on the shortage? Are there varying levels of shortage that will impact practice in different ways?

- 5.2.3. What type of services will be impacted by the Critical Resource Shortage?

- 5.2.4. How will these services change during the Critical Resource Shortage?

- 5.2.5. Will the change in service depend on the severity of the Critical Resource Shortage? In other words, will there be different plans or protocols that apply to different severities of Critical Resource Shortages?

- 5.2.6. How will patients be triaged for the Critical Resource in question? What patients will receive the Critical Resource first, second, third, etc.? Refer to the ethical principles established in Section 3.

- 5.2.7. When there is a Critical Resource Shortage, what criteria will determine whether the patient is given the resource? Is there any literature to guide the development of these criteria? See Appendix 3.

- 5.2.8. What criteria will dictate that a patient should not receive the resource as a result of the Critical Resource Shortage? Is there any literature to guide this decision? See Appendix 3.

- 5.2.8.1. Refer to decisions made in Section 3.6 regarding those criteria that should not be used to justify withholding a Critical Resource from a patient.

- 5.2.9. If applicable pursuant to your facility's established ethical principles as defined in Section 3.3 and to the Critical Resource in question, under what clinical circumstances will the hospital/provider withdraw the Critical Resource from one

patient to give to another patient for whom use of the Critical Resource is more appropriate?

- 5.2.10. Based on decisions made in Sections 3.4 and 3.5, what specific resources will be provided to those patients who will not receive the Critical Resource?
- 5.2.11. If in Section 4.1.6.1 the facility decided to use a designated person(s) to make allocation decisions who is chosen based on the Critical Resource being allocated, who is the appropriate person(s) for this resource?
- 5.2.12. Which types of providers (MDs, RNs, LPNs) will use the Critical Resource in question to provide care?
- 5.2.13. What type of training is needed pre-event to aid implementation of the specific Critical Resource Shortage Response Plan? What training will be conducted at the time of the event to aid implementation or allow for those not typically involved in using this Critical Resource to become involved (“just-in-time” training)?
- 5.2.14. What specific documentation is required to document services rendered pursuant to the Critical Resource Shortage Response Plan based on the definition of “essential documentation” determined in Section 4.1.10? How will this documentation be captured during the Emergency?

Critical Shortage of Physical Space:

- 5.3. Using the ethical and operational principles developed in Sections 3 and 4 of this Planning Guide, respectively, each small group should address the following issues with respect to a critical shortage of *physical space* in the facility to create a Critical Resource Shortage Response Plan.
 - 5.3.1. At what point will a critical shortage of physical space exist? At what point will clinicians have to change their practice based on the shortage?
 - 5.3.2. What type of services will be impacted by the critical shortage of physical space?
 - 5.3.3. How will these services change during the critical shortage of physical space?
 - 5.3.4. What alternative locations can be used to provide services to patients during the critical shortage?
 - 5.3.4.1. When choosing alternative locations, the following should be taken into consideration.
 - 5.3.4.1.1. What utilities (e.g. medical gases, electricity, water, communication capabilities) are needed? Are these already available in the alternative location? If not, can they quickly be made available in the alternative location?
 - 5.3.4.1.2. Are there any support services (e.g. OR recovery space) that need to be in close proximity to the service that is being displaced?

- 5.3.4.1.3. For what is the alternative location currently being used? Is there equipment, furniture, or people that will need to be moved from that space in order to use it?
- 5.3.4.1.4. Will existing patients be transferred to the alternative location, or will only new patients be treated in the alternative location? If existing patients will be transferred, how will this be accomplished?
- 5.3.4.2. Potential locations for alternative space may include administrative space, conference rooms, medical office buildings, or space where non-essential services have been discontinued for the duration of the Emergency or Disaster.

Critical Personnel Shortage:

- 5.4. Using the ethical and operational principles developed in Sections 3 and 4 of this Planning Guide, respectively, each small group should address the following issues with respect to a *critical personnel shortage* to create a Critical Resource Shortage Response Plan.
 - 5.4.1. Does the hospital already have a plan in place to mitigate the critical personnel shortage? If not, such a plan should be created. If so, the remainder of this planning process assumes that mitigation is no longer a feasible option.
 - 5.4.1.1. This will require an evaluation of the facility's "surge" plan and its plans to share human resources with other facilities and to obtain additional human resources through volunteers and medical reserve corps in its region.
 - 5.4.2. At what point will a critical personnel shortage exist? At what point will clinicians have to change their practice based on the shortage? Are there varying levels of shortage that will impact practice in different ways?
 - 5.4.3. What services will be impacted by the critical personnel shortage?
 - 5.4.4. How will these services change during the critical personnel shortage? Will certain services cease, while others expand or are reduced?
 - 5.4.5. Will the change in services depend on the severity of the critical personnel shortage? In other words, will there be different plans or protocols that apply to different severities of critical personnel shortages?
 - 5.4.6. How will patients be triaged for services provided by the critical personnel in question? What patients will receive the services first, second, third, etc.? Refer to the ethical principles established in Section 3.
 - 5.4.7. When there is a critical personnel shortage, what criteria will be used to determine whether the patient is treated by the critical personnel? Is there any literature to guide the development of these criteria? See Appendix 3.

- 5.4.8. What criteria will be used to determine that a patient should not be treated by the critical personnel as a result of the critical personnel shortage? Is there any literature to guide this decision? See Appendix 3.
- 5.4.8.1. Refer to decisions made in Section 3.6 regarding those criteria that should not be used to justify withholding a Critical Resource from a patient.
- 5.4.9. For those patients who will not be treated by the critical personnel, will they be treated by another category of staff member in the facility? By a family member? By volunteers? By nonclinical personnel?
- 5.4.10. Can the number and type of delegable duties be expanded to help address the critical personnel shortage?
- 5.4.10.1. Do your facility's policies limit licensed personnel's scope of practice more than that required by statute? If so, can the policies be amended during a critical personnel shortage to allow licensed personnel to do more? How, if at all, can licensed providers obtain expanded privileges during a critical personnel shortage to address the problem?
- 5.4.11. What type of training is needed pre-event to aid implementation of the specific Critical Resource Shortage Response Plan? What training will you conduct at the time of the event to aid implementation or allow for those not typically involved in providing these services to become involved ("just-in-time" training)?
- 5.4.12. Will a critical personnel shortage affect the ability to produce "essential documentation" as defined in Section 4.1.10? If so, what can be done to ensure that "essential documentation" is completed during the critical personnel shortage?
- 5.5. Once the group has answered all the questions in either Section 5.2, 5.3 or 5.4, depending on the resource in question, to their satisfaction, they will have created the content of a Critical Resource Shortage Response Plan. This content should be reduced to writing in the form of a policy.
- 5.6. Present the policy to the group(s) that conducted the Critical Resource Vulnerability Analysis for discussion, revision and approval.
- 5.7. Present the policy to the Medical Staff for approval.
- 5.8. Present the policy to the appropriate governing body(ies) for approval.
- 5.9. Add the policy to the appropriate Hospital policy manual(s) and incorporate into the facility's EOP.
- 5.10. Educate and train physicians and staff on the use of the Critical Resource Shortage response policy and documentation required.

Triage Protocols:

6. Develop triage protocols that will be used in Emergency and Disaster situations.
 - 6.1. Convene a group or use an existing group composed of at least a facilitator, at least two emergency room physicians, an emergency room nurse, IC Medical Control (e.g. operations-clinical and mass care), a palliative care specialist (if available), EMS representatives, an administrative representative, and a representative from the ethics committee.
 - 6.2. Group will:
 - 6.2.1. Determine at what capacity levels current triage mechanisms will not be appropriate or practical. The group may choose to take a tiered approach to answering this question by designating several “breaking point” capacities. When determining “breaking points,” the group should take into account at least the following:
 - 6.2.1.1. Number of patients presenting;
 - 6.2.1.2. Time frame of the influx of patients (e.g. hours v. days v. weeks);
 - 6.2.1.3. Method of presentation (e.g. EMS v. self-refer);
 - 6.2.1.4. Severity of expected injury/illness;
 - 6.2.1.5. Number of staff available;
 - 6.2.1.6. Number of beds available;
 - 6.2.1.7. Amount of space for waiting patients; and,
 - 6.2.1.8. Location of triage.
 - 6.2.2. Review the several existing triage systems, including:
 - 6.2.2.1. Emergency Severity Index (ESI): Five-level emergency department triage algorithm that divides patients into five groups from 1 - most urgent to 5 - least urgent on the basis of acuity and resource needs. The handbook can be downloaded at <http://www.ahrq.gov/research/esi/#download>.
 - 6.2.2.2. START Triage: START stands for "Simple Triage and Rapid Treatment." Using the START program, patients can be triaged in 60 seconds or less. Information on this can be found on their website at <http://www.start-triage.com>.
 - 6.2.2.3. JumpSTART Pediatric Multiple Casualty Incident Triage: This is similar to the START triage program, but is specifically designed to triage children. More information can be found on the website at <http://www.jumpstarttriage.com/>.
 - 6.2.2.4. START, then SAVE: This takes the START system to a secondary triage level of SAVE ("Secondary Assessment of Victim Endpoint").
 - 6.2.2.5. MASS Triage: "Move, Assess, Sort, Send" This system utilizes US military triage categories with a proven means of handling large numbers of

casualties in a mass casualty incident. "Id-me!" (Immediate, Delayed, Minimal, Expectant) is used to sort patients while using the MASS triage model.

- 6.2.3. Determine which triage protocols (existing or new) should be implemented at each "breaking point" identified.
- 6.2.4. Based on decisions made in Sections 3.4 and 3.5, what specific resources will be provided to those patients triaged to a non-treatment category (e.g. expectant)?
- 6.3. Once the group reaches consensus on the above issues, Emergency and Disaster triage protocol policies should be drafted.
- 6.4. Present the policy to the group(s) that conducted the Critical Resource Vulnerability Analysis for discussion, revision and approval.
- 6.5. Present the policy to the Medical Staff for approval.
- 6.6. Present the policy to the appropriate governing body(ies) for approval.
- 6.7. Add the policy to the appropriate Hospital policy manual(s) and incorporate into the hospital's EOP, including the Mass Casualty Incident Annex, if applicable.
- 6.8. Create any forms that are needed to use the triage system effectively.
- 6.9. Educate and train physicians and staff on the use of the Emergency and Disaster triage policy.

Ad Hoc Critical Resource Shortage Response Plans:

In an Emergency/Disaster situation, unforeseen Critical Resources will become scarce leading to a need to implement Critical Resource Shortage Response Plans. Because by definition these shortages are unforeseen, the hospital cannot create specific Critical Resource Shortage Response Plans ahead of time. Hospitals can use the following process to determine Critical Resource Shortage Response Plans to respond to these unforeseen Critical Resource Shortages during an Emergency/Disaster.

NOTE: It is possible that hospitals will not have had the opportunity to develop plans for Critical Resources identified in the Critical Resource analysis. The process described below can be used for shortages of these Critical Resources as well.

7. Create mechanisms to operationalize the creation of Critical Resource Shortage Response Plans for resources for which no plan is pre-existing during an event.
 - 7.1. Identify individuals who will be called upon to develop Critical Resource Shortage Response Plans in the midst of an Emergency or Disaster.
 - 7.1.1. Identify and prioritize at least two representatives from the ethics committee.
 - 7.1.2. Identify and prioritize at least two administrators.
 - 7.1.3. Identify and prioritize physicians from each specialty represented on the Medical Staff.

- 7.1.4. Notify all identified individuals that they have been so identified, explain the scope of their responsibilities during an Emergency or Disaster, obtain signed agreement that the individuals will fulfill their duties during the Emergency or Disaster.
- 7.2. Create a contact list for all identified individuals that is to be kept with all other EOP materials.
- 7.3. Review the hospital's bylaws to ensure that in the event of an Emergency or Disaster, a few members of the governing body are vested with the authority to approve an ad hoc Critical Resource Shortage Response Plan. If this power does not exist, the bylaws should be amended to so provide.

Modify EOP and ICS:

8. Modify the EOP and ICS to reflect the incorporation of Critical Resource Shortage Response Plans (including operational considerations, ethical principles, pre-existing plans, and mechanisms for the creation of ad hoc plans) and triage protocols.
 - 8.1. Modify the EOP to reflect the command support function responsible for declaring a Critical Resource Shortage (See Section 4.1.3).
 - 8.2. Modify the EOP to reflect the command support function responsible for authorizing implementation of a pre-existing Critical Resource Shortage Response Plan.
 - 8.3. Modify the EOP to reflect the command support function responsible for convening the group that will create a Critical Resource Shortage Response Plan to address a Critical Resource Shortage for which no plan currently exists.
 - 8.4. Modify the EOP so that existing Emergency information distribution mechanisms can be used to distribute information about the implementation, content and eventual termination of Critical Resource Shortage Response Plans (See Section 4.1.11).
 - 8.5. If applicable, modify the EOP to recognize the role of designated person(s) who will be making triage decisions (See Section 4.1.6).
 - 8.6. Create a mechanism for reporting noncompliance with Critical Resource Shortage Response Plans within the ICS.

Educate Staff:

9. Educate medical staff and hospital staff on at least the following issues concerning Critical Resource Shortage Response Plans.
 - 9.1. The need for Critical Resource Shortage Response Plans during an Emergency or Disaster and the importance of complying with Critical Resource Shortage Response Plans when they are issued.
 - 9.2. Process for determining and implementing Critical Resource Shortage Response Plans prior to Emergency or Disaster.

- 9.3. Content of any existing or developed Critical Resource Shortage Response Plans policies.
- 9.4. Process for determining and implementing Critical Resource Shortage Response Plans during an Emergency or Disaster.
- 9.5. Medical Staff should be told about the list of physicians who will be called upon to develop Critical Resource Shortage Response Plans in the midst of an Emergency or Disaster.
- 9.6. All clinicians should be educated on the mechanism for reporting noncompliant behavior with Critical Resource Shortage Response Plans and the ramifications of noncompliance.
- 9.7. All providers should be educated on the role and responsibilities of the designated person(s) who will be making triage decisions (See Section 4.1.6), if applicable.
- 9.8. Liability protections available to those who render care during Emergency or Disaster circumstances (both in terms of civil liability and loss of licensure).

Exercise/Drill:

10. Exercise/drill

- 10.1. Conduct an initial exercise/drill to test the following:
 - 10.1.1. Response to a Critical Resource Shortage for which a response plan already exists; and
 - 10.1.2. Response to a Critical Resource Shortage for which a response plan does not already exist.
- 10.2. Modify plans, policies and process as appropriate based on findings of the exercise/drill.
- 10.3. Exercise Critical Resource Shortages at least once a year as part of the facility's semi-annual exercise.

Intra-Event/Response Phase:

Report Critical Resource Shortage:

11. A resource shortage is reported through the ICS to the person that the facility has designated in Section 4.1.2.

Determine Whether There Is An Existing Critical Resource Shortage Response Plan:

12. The person designated in Section 4.1.2 determines whether there is a pre-existing Critical Resource Shortage Response Plan to address the resource in question.
 - 12.1. If such a plan does exist:
 - 12.1.1. Determine whether the amount of remaining resource constitutes a Critical Resource Shortage (e.g. has the facility already exhausted all possible mitigation avenues?).
 - 12.1.2. If it is determined that there is a Critical Resource Shortage, implement the facility disaster plan (if it is not already activated) and the appropriate Critical Resource Shortage Response Plan, and notify the local EOC (if the facility has not done so already).
 - 12.1.3. Communicate implementation of the Critical Resource Shortage Response Plan to the medical staff and all personnel through pre-established EOP and ICS mechanisms.
 - 12.1.4. Conduct any appropriate and necessary “just-in-time” training as identified in Section 5.2.13.
 - 12.1.5. Monitor the level of resource and use of the Critical Resource Shortage Response Plan.
 - 12.1.6. Determine whether the Critical Resource Shortage Response Plan needs modification during the event and modify accordingly (See Section 4.1.7).
 - 12.1.6.1. During each operational period, the person(s) designated in Section 4.1.7.1 should review the Critical Resource Shortage situation, the use of the plan and the results, and make recommendations to the person(s) designated in Section 4.1.7.2.
 - 12.1.6.2. Evaluate whether there are any circumstances that were not contemplated and which require the plan to be modified.
 - 12.1.7. Terminate the Critical Resource Shortage Response Plan when the hospital is no longer experiencing shortage.
 - 12.1.8. Notify the EOC of termination of the Critical Resource Shortage Response Plan.
 - 12.2. If such a plan does not exist, see Section 13.

If a Plan Does Not Exist, Determine Whether A Critical Resource Shortage Exists:

13. Determine whether a Critical Resource Shortage exists.

13.1. Determine whether a specific resource is a “Critical Resource” by asking whether that resource is necessary to sustain human life, prevent permanent injury/disability or stabilize a patient experiencing a medical emergency?

13.1.1. If the answer is yes, then the resource is a Critical Resource.

13.1.2. If the answer is no, then the resource is not a Critical Resource and this Guidance is not applicable.

13.2. Determine whether a Critical Resource Shortage exists by asking whether the Critical Resource was depleted as a result of an Emergency/Disaster to the extent that the remaining resources will not allow the hospital to treat remaining patients in accordance with the traditional standard of care.

13.3. Validate reports of resource shortages.

13.4. Once validated:

13.4.1. Determine whether the shortage can be quickly mitigated by using resources from a sister facility, a neighboring facility (as identified by the RHCC or the EOC) or pursuant to an MOU.

13.4.2. If it cannot be mitigated:

13.4.2.1. Implement facility disaster response plan (if it has not already been implemented).

13.4.2.2. Notify the local EOC that Critical Resource Shortage Response Plans are being implemented (if the EOC has not already been notified).

13.4.2.3. Go to Section 14 to develop an ad hoc Critical Resource Shortage plan.

Develop Ad Hoc Critical Resource Shortage Response Plan:

14. Develop the ad hoc Critical Resource Shortage Response Plan. For critical shortages of material resources, refer to Section 14.2. For a critical shortage of physical space, refer to Section 14.3. For a critical personnel shortage, refer to Section 14.4.

14.1. Use the contact list created in Section 7.2 to convene the group which will create a Critical Resource Shortage Response Plan for those resources which have been depleted and for which no plan currently exists. [This will require identification of the specialties that will be affected by the Critical Resource Shortage so that the relevant clinicians can be contacted.]

Critical Shortage of Material Resources:

- 14.2. In developing the ad hoc Critical Resource response plan for a critical shortage of *material resources* (e.g. equipment, medications), the group should address the following issues.
- 14.2.1. What services will be impacted by the Critical Resource Shortage?
 - 14.2.2. How will these services change during the Critical Resources shortage?
 - 14.2.3. How will patients be triaged for the Critical Resource in question? What patients will receive the Critical Resource first, second, third, etc? Refer to the ethical principles established in Section 3.
 - 14.2.4. What criteria will determine whether the patient is given the Critical Resource? Is there any literature to guide the development of these criteria? See Appendix 3.
 - 14.2.5. What criteria will dictate that a patient should not receive the Critical Resource? Is there any literature to guide this decision? See Appendix 3.
 - 14.2.5.1. Refer to decisions made in Section 3.6 regarding those criteria that should not be used to justify withholding a Critical Resource from a patient.
 - 14.2.6. If applicable pursuant to your facility's established ethical principles as defined in Section 3.3 and to the Critical Resource in question, under what clinical circumstances will the hospital/provider withdraw the Critical Resource from one patient to give to another patient for whom use of the Critical Resource is more appropriate?
 - 14.2.7. Based on decisions made in Sections 3.4 and 3.5, what specific resources will be provided to those patients who will not receive the Critical Resource?
 - 14.2.8. If in Section 4.1.6.1, the facility decided to use a designated person(s) to make allocation decisions who is chosen based on the specific Critical Resource, who is the appropriate person(s) for this Critical Resource?
 - 14.2.9. Which types of providers (MDs, RNs, LPNs) will use the Critical Resource in question to provide care?
 - 14.2.10. What type of just-in-time training is needed to aid implementation of the specific Critical Resource Shortage Response Plan?
 - 14.2.11. What specific documentation is required to document services rendered pursuant to the Critical Resource Shortage Response Plan based on the definition of "essential documentation" determined in Section 4.1.10? How will this documentation be captured?

Critical Shortage of Physical Space:

- 14.3. In developing the ad hoc Critical Resource response plan for a critical shortage of *physical space*, the group should address the following issues.
- 14.3.1. What type of services will be impacted by the critical shortage of physical space?
 - 14.3.2. What alternative locations can be used to provide services to patients during the critical shortage?
 - 14.3.3. When choosing alternative locations, the following should be taken into consideration.
 - 14.3.3.1. What utilities (e.g. medical gases, electricity, water, communication capabilities) are needed? Are those already available in the alternative location? If not, can they quickly be made available in the alternative location?
 - 14.3.3.2. Are there any support services (e.g. OR recovery space) that need to be in close proximity to the service that is being displaced?
 - 14.3.3.3. For what is the alternative location space currently being used? Is there equipment, furniture, or people that will need to be moved from that space in order to use it?
 - 14.3.3.4. Will existing patients be transferred to the alternative location, or will only new patients be treated in the alternative location? If existing patients will be transferred, how will this be accomplished?
 - 14.3.4. Potential locations for alternative space may include administrative space, conference rooms, medical office buildings, or space where non-essential services have been discontinued for the duration of the Emergency or Disaster.

Critical Personnel Shortage:

- 14.4. In developing the ad hoc Critical Resource response plan for a *critical personnel shortage*, the group should address the following issues.
- 14.4.1. What services will be impacted by the critical personnel shortage?
 - 14.4.2. How will these services change during the critical personnel shortage?
 - 14.4.3. How will patients be triaged for the services provided by the critical personnel in question? What patients will receive services first, second, third, etc.? Refer to the ethical principles established in Section 3.
 - 14.4.4. What criteria will be used to determine whether the patient is treated by the critical personnel? Is there any literature to guide the development of these criteria? See Appendix 3.

- 14.4.5. What criteria will be used to determine that a patient should not be treated by the critical personnel? Is there any literature to guide this decision? See Appendix 3.
 - 14.4.5.1. Refer to decisions made in Section 3.6 regarding those criteria that should not be used to justify withholding a Critical Resource from a patient.
 - 14.4.6. For those patients who will not be treated by the critical personnel, will they be treated by another category of staff member in the facility?
 - 14.4.7. Can the number and type of delegable duties be expanded to help address the critical personnel shortage?
 - 14.4.7.1. Do your facility's policies limit licensed personnel's scope of practice more than that required by statute? If so, can the policies be amended during a critical personnel shortage to allow licensed personnel to do more? How, if at all, can licensed providers obtain expanded privileges during a critical personnel shortage to address the problem?
 - 14.4.8. Will a critical personnel shortage affect the ability to produce "essential documentation" as defined in Section 4.1.10? If so, what can be done to ensure that "essential documentation" is completed during the critical personnel shortage?
-
- 14.5. Once the group has developed an ad hoc Critical Resource response plan pursuant to Sections 14.2, 14.3 or 14.4, depending on the resource in question, it should be reduced to writing for easy dissemination.
 - 14.6. If the Medical Staff leadership is not represented in the ad hoc group, (s)he should be given a copy of the Critical Resource Shortage Response Plan for information purposes only.
 - 14.7. Present the plan to the appropriate governing body(ies) for approval.
 - 14.8. Inform medical staff and other appropriate personnel of the content of the ad hoc Critical Resource Shortage Response Plan through the mechanism developed in Section 4.1.11.

Implement Critical Resource Shortage Response Plan:

- 15. Implement the Critical Resource Shortage Response Plan pursuant to the mechanism created in Section 4.1.

Modify Critical Resource Shortage Response Plan:

- 16. Modify the Critical Resource Shortage Response Plan, if needed, pursuant to Section 4.1.6 and 12.1.6.

Terminate Critical Resource Shortage Response Plan:

17. Terminate the Critical Resource Shortage Response Plan pursuant to the mechanism created in Section 4.1.8 and 4.1.9.

Post-Event/Recovery Phase:

Psychological Support:

18. Provide psychological support services to employees, staff and physicians (refer to Section 4.1.13).

Evaluate Critical Resource Shortage Response Plans:

19. Evaluate the use and effectiveness of Critical Resource Shortage Response Plans and processes.

Modify Critical Resource Shortage Response Plans:

20. Modify plans and processes as appropriate based on actual experiences during the event.

Patient and Family Support:

21. Provide support and recovery services to patients and their families (refer to Section 4.1.13).

Appendix 1: Title 44 Definitions²

Communicable disease of public health threat: means an illness of public health significance, as determined by the State Health Commissioner in accordance with regulations of the Board of Health, caused by a specific or suspected infectious agent that may be reasonably expected or is known to be readily transmitted directly or indirectly from one individual to another and has been found to create a risk of death or significant injury or impairment; this definition shall not, however, be construed to include human immunodeficiency viruses or tuberculosis, unless used as a bioterrorism weapon.

Disaster: means (i) any man-made disaster including any condition following an attack by any enemy or foreign nation upon the United States resulting in substantial damage of property or injury to persons in the United States and may be by use of bombs, missiles, shell fire, nuclear, radiological, chemical, or biological means or other weapons or by overt paramilitary actions; terrorism, foreign and domestic; also any industrial, nuclear, or transportation accident, explosion, conflagration, power failure, resources shortage, or other condition such as sabotage, oil spills, and other injurious environmental contaminations that threaten or cause damage to property, human suffering, hardship, or loss of life; and (ii) any natural disaster including any hurricane, tornado, storm, flood, high water, wind-driven water, tidal wave, earthquake, drought, fire, communicable disease of public health threat, or other natural catastrophe resulting in damage, hardship, suffering, or possible loss of life.

Emergency: means any occurrence, or threat thereof, whether natural or man-made, which results or may result in substantial injury or harm to the population or substantial damage to or loss of property or natural resources and may involve governmental action beyond that authorized or contemplated by existing law because governmental inaction for the period required to amend the law to meet the exigency would work immediate and irrevocable harm upon the citizens or the environment of the Commonwealth or some clearly defined portion or portions thereof.

Local emergency: means the condition declared by the local governing body when in its judgment the threat or actual occurrence of an emergency or disaster is or threatens to be of sufficient severity and magnitude to warrant coordinated local government action to prevent or alleviate the damage, loss, hardship or suffering threatened or caused thereby; provided, however, that a local emergency arising wholly or substantially out of a resource shortage may be declared only by the Governor, upon petition of the local governing body, when he deems the threat or actual occurrence of such an emergency or disaster to be of sufficient severity and magnitude to warrant coordinated local government action to prevent or alleviate the damage, loss, hardship, or suffering threatened or caused thereby; provided, however, nothing in this chapter shall be construed as prohibiting a local governing body from the prudent management of its water supply to prevent or manage a water shortage.

² These definitions have been revised for consistency with recently approved legislation (HB 403) which will go into effect on July 1, 2008.

Major disaster: means any natural catastrophe, including any: hurricane, tornado, storm, high water, wind-driven water, tidal wave, tsunami, earthquake, volcanic eruption, landslide, mudslide, snowstorm or drought, or regardless of cause, any fire, flood, or explosion, in any part of the United States, which, in the determination of the President of the United States is, or thereafter determined to be, of sufficient severity and magnitude to warrant major disaster assistance under the Stafford Act (P.L. 93-288 as amended) to supplement the efforts and available resources of states, local governments, and disaster relief organizations in alleviating the damage, loss, hardship, or suffering caused thereby and is so declared by him.

Appendix 2: Examples of Critical Resources

- Ventilators
- Operating Rooms
- Blood
- Oxygen
- Anti-virals
- Burn care kits
- Suture kits
- IVs
- Morphine
- Defibrillators
- Negative Pressure or HEPA-filtered Isolation Spaces
- Antibiotics
- PPE
- Linens
- Imaging Devices
- Beds
- Chest tubes
- Code carts
- Normal saline
- Splints
- Operating Rooms
- Respiratory Therapists

Appendix 3: Critical Resource Shortage Planning Literature

- AHRQ's *Altered Standards of Care in Mass Casualty Events* (April 2005)
- HHS *Pandemic Influenza Plan* (November 2005)
- Institute of Medicine's *Modeling Community Containment for Pandemic Influenza: A Letter Report* (2006)
- Institute of Medicine's *Reusability of Facemasks During an Influenza Pandemic: Facing the Flu* (2006)
- WHO *Rapid Advice Guidelines on Pharmacological Management of Humans Infected with Avian Influenza A (H5N1) Virus* (2006)
- WHO's *Global Consultation on Addressing Ethical Issues in Pandemic Influenza Planning* (October 2006)
- AHRQ's *Providing Mass Medical Care with Scarce Resources: A Community Planning Guide* (November 2006)
- Ontario Health Plan for Influenza Pandemic's *Development of a Triage Protocol for Critical Care During an Influenza Pandemic* (November 2006)
- CDC's *Interim Pre-pandemic Planning Guidance: Community Strategy for Pandemic Influenza Mitigation in the U.S. – Early, Targeted, Layered Use of Nonpharmaceutical Interventions* (February 2007)
- New York Department of Health's *Allocation of Ventilators in an Influenza Pandemic: Planning Document* (March 2007)
- North Carolina Institute of Medicine's *Stockpiling Solutions: NC's Ethical Guidelines for an Influenza Pandemic* (April 2007)
- CDC and DHHS' *In a Moment's Notice: Surge Capacity for Terrorist Bombings – Challenges and Proposed Solutions* (April 2007)
- WHO *Interim Protocol: Rapid Operations to Contain the Initial Emergence of Pandemic Influenza* (May 2007)
- California Department of Health Services' *Development of Standards and Guidelines for Healthcare Surge during Emergencies* (mid 2007)
- Security and Prosperity Partnership of North America's *North American Plan for Avian & Pandemic Influenza* (August 2007)
- GAO's *Influenza Pandemic: Opportunities Exist to Address Critical Infrastructure Protection Challenges That Require Federal and Private Sector Coordination* (October 2007)
- CDC's *Proposed Considerations for Antiviral Drug Stockpiling by Employers in Preparation for an Influenza Pandemic* (draft, October 2007)
- CDC's *Proposed Guidance on Antiviral Drug Use Strategies During an Influenza Pandemic* (draft, November 2007)
- OSHA's *Guidance on Preparing Workplaces for an Influenza Pandemic* (2007)
- OSHA's *Pandemic Influenza Preparedness and Response Guidance for Healthcare Workers and Healthcare Employers* (2007)
- ACLU's *Pandemic Preparedness: The Need for a Public Health – Not a Law Enforcement/National Security – Approach* (January 2008)

- CDC's *Influenza Pandemic Operation Plan* (January 2008)
- Task Force for Mass Critical Care Summit Report, published in *Chest* (May 2008)
- Harvard School of Public Health and Massachusetts Department of Public Health Altered Standards of Care Survey (current in process)

APPENDIX G

FEMA DISASTER ASSISTANCE POLICY – *EMERGENCY ASSISTANCE FOR HUMAN INFLUENZA PANDEMIC*



FEMA

DISASTER ASSISTANCE POLICY

DAP9523.17

I. TITLE: Emergency Assistance for Human Influenza Pandemic

II. DATE: March 31, 2007

III. PURPOSE:

Establish the types of emergency protective measures that are eligible under the Public Assistance Program during a Federal response to an outbreak of human influenza pandemic in the U.S. and its territories.

IV. SCOPE AND AUDIENCE:

The policy is applicable to all major disasters and emergencies declared on or after the date of publication of this policy. It is intended for personnel involved in the administration of the Public Assistance Program.

V. AUTHORITY:

Sections 403 (42 U.S.C. 5121-5206) and 502 (42 U.S.C. 5192) respectively, of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act), and 44 Code of Federal Regulations (CFR) §206.225(a)(3)(i).

VI. BACKGROUND:

A. The severity of the next human influenza pandemic cannot be predicted, but modeling studies suggest that the impact of a pandemic on the United States could be substantial. In the absence of any control measures (vaccination or drugs), it has been estimated that in the United States a “medium-level” pandemic could cause 89,000 to 207,000 deaths, 314,000 to 734,000 hospitalizations, 18 to 42 million outpatient visits, and another 20 to 47 million people being sick. Over an expected period of two years, between 15% and 35% of the U.S. population could be affected by an influenza pandemic, and the economic impact could range between \$71.3 and \$166.5 billion. This effect does not include members of the general population that may have to miss work to care for ill family members, potentially raising the population affected by an influenza pandemic to 55% during the peak weeks of community outbreak (Department of Health and Human Services, Centers for Disease Control and Prevention, Pandemic Flu: Key Facts, January 17, 2006).



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DISASTER ASSISTANCE POLICY

DAP9523.17

B. An influenza pandemic differs from other public health threats, in that:

- A pandemic will last much longer than most public health emergencies, and may include “waves” of influenza activity separated by months (in 20th century pandemics, a second wave of influenza activity occurred 3 to 12 months after the first wave).
- The numbers of health-care workers and first responders available to work is expected to be reduced. This population will be at high risk of illness through exposure in the community and in health-care settings.
- Resources in many locations could be limited, depending on the severity and spread of an influenza pandemic.

C. Assumptions:

1. Three conditions must be met for a pandemic to begin:
 - a. A new influenza virus subtype must emerge, for which there is little or no human immunity. (For example, the H5N1 virus (bird flu) is a new virus for humans. It has never circulated widely among people, infecting more than 200 humans, but killing over half of them.)
 - b. It must infect humans and cause illness; and:
 - c. It must spread easily and sustainably (continue without interruption) among humans.
2. There will be large surges in the number of people requiring or seeking medical or hospital treatment, which could overwhelm health services.
3. High rates of worker absenteeism will interrupt other essential services, such as emergency response, communications, fire and law enforcement, and transportation, even with Continuity of Operations Plans in place.
4. Rates of illness are expected to peak fairly rapidly within a given community, because all populations will be fully susceptible to an H5N1-like virus.
5. Local social and economic disruptions may be temporary, yet have amplified effects due to today’s closely interrelated and interdependent systems of trade and commerce.



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6. A second wave of global spread should be anticipated within a year, based on past experience.

7. All countries are likely to experience emergency conditions during a pandemic, leaving few opportunities for international assistance, as seen during natural disasters or localized disease outbreaks. Once international spread has begun, governments will likely focus on protecting domestic populations.

VII. POLICY:

A. The following Emergency Protective Measures (Category B) may be eligible for reimbursement to State and local governments and certain private non-profit organizations:

1. Activation of State or local emergency operations center to coordinate and direct the response to the event.
2. Purchase and distribution of food, water, ice, medicine, and other consumable supplies.
3. Management, control, and reduction of immediate threats to public health and safety.
4. Movement of supplies and persons.
5. Security forces, barricades and fencing, and warning devices.
6. Emergency medical care (non-deferrable medical treatment of disaster victims in a shelter or temporary medical facility and related medical facility services and supplies, including emergency medical transport, X-rays, laboratory and pathology services, and machine diagnostic tests for a period determined by the Federal Coordinating Officer).
7. Temporary medical facilities (for treatment of disaster victims when existing facilities are overloaded and cannot accommodate the patient load).
8. Congregate sheltering (for disaster victims when existing facilities are overloaded and cannot accommodate the patient load).
9. Communicating health and safety information to the public.



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10. Technical assistance to State and local governments on disaster management and control.

11. Search and rescue to locate and recover members of the population requiring assistance and to locate and recover human remains.

12. Storage and internment of unidentified human remains.

13. Mass mortuary services.

14. Recovery and disposal of animal carcasses (except if another federal authority funds the activity – e.g., U.S. Department of Agriculture, Animal, Plant and Health Inspection Service provides for removal and disposal of livestock).

B. Eligible Costs. Overtime pay for an applicant's regular employees may be eligible for reimbursement. The straight-time salaries of an applicant's regular employees who perform eligible work are not eligible for reimbursement. Regular and overtime pay for extra-hires may be eligible for reimbursement. Eligible work accomplished through contracts, including mutual aid agreements, may be eligible for reimbursement. Equipment, materials, and supplies made use of in the accomplishment of emergency protective measures may be eligible.

C. Ineligible Costs. Ineligible costs include the following:

1. Definitive care (defined as medical treatment or services beyond emergency medical care, initiated upon inpatient admissions to a hospital).

2. Cost of follow-on treatment of disaster victims is not eligible, in accordance with FEMA Recovery Policy 9525.4 – Medical Care and Evacuation.

3. Costs associated with loss of revenue.

4. Increased administrative and operational costs to the hospital due to increased patient load.

5. Rest time for medical staff. Rest time includes the time a staff member is unavailable to provide assistance with emergency medical care.

6. Because the law does not allow disaster assistance to duplicate insurance benefits, disaster assistance will not be provided for damages covered by insurance. The PA applicant



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should not seek reimbursement for these costs if underwritten by private insurance, Medicare, Medicaid or a pre-existing private payment agreement.

Note: Ineligible costs remain ineligible even if covered under contract, mutual aid, or other assistance agreements.

D. Coordination with Emergency Support Function (ESF). Coordination among ESFs 3, 5, 6, 8, 9, 11, and 14 will be required.

VIII. ORIGINATING OFFICE: Recovery Division (Public Assistance Branch).

IX. SUPERSESION: This policy supersedes all previous guidance on this subject.

X. REVIEW DATE: Three years from date of publication.

A handwritten signature in blue ink, appearing to read "David Garratt", written over a horizontal line.

David Garratt
Acting Assistant Administrator
Disaster Assistance Directorate

APPENDIX H

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES HIPAA FAQ'S

U.S. Department of Health & Human Services

Is the HIPAA Privacy Rule suspended during a national or public health emergency?

Answer:

No; however, the Secretary of HHS may waive certain provisions of the Rule under the Project Bioshield Act of 2004 (PL 108-276) and section 1135(b)(7) of the Social Security Act.

What provisions may be waived

If the President declares an emergency or disaster *and* the Secretary declares a public health emergency, the Secretary may waive sanctions and penalties against a covered hospital that does not comply with certain provisions of the HIPAA Privacy Rule:

1. the requirements to obtain a patient's agreement to speak with family members or friends involved in the patient's care (45 CFR 164.510(b))
2. the requirement to honor a request to opt out of the facility directory (45 CFR 164.510(a))
3. the requirement to distribute a notice of privacy practices (45 CFR 164.520)
4. the patient's right to request privacy restrictions (45 CFR 164.522(a))
5. the patient's right to request confidential communications (45 CFR 164.522(b))

When and to what entities does the waiver apply

If the Secretary issues such a waiver, it only applies:

1. In the emergency area and for the emergency period identified in the public health emergency declaration.
2. To hospitals that have instituted a disaster protocol. The waiver would apply to all patients at such hospitals.
3. For up to 72 hours from the time the hospital implements its disaster protocol.

When the Presidential or Secretarial declaration terminates, a hospital must then comply with all the requirements of the Privacy Rule for any patient still under its care, even if 72 hours has not elapsed since implementation of its disaster protocol.

Regardless of the activation of an emergency waiver, the HIPAA Privacy Rule permits disclosures for treatment purposes and certain disclosures to disaster relief organizations. For instance, the Privacy Rule allows covered entities to share patient information with the American Red Cross so it can notify family members of the patient's location. See 45 CFR 164.510(b)(4).

Learn More:

- See <http://www.hhs.gov/ocr/hipaa/KATRINANHIPAA.pdf> for information on sharing information in emergency situations.

Last Updated: 10/03/2008